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Counsel for Petitioner
W. SCOTT HARKONEN

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

~~CR 11 4268 TEH~~

W. SCOTT HARKONEN, Petitioner, v. UNITED STATES OF AMERICA, Respondent.	Case No. CR 08-0164 MHP

EXHIBITS IN SUPPORT OF
PETITION FOR WRIT OF ERROR CORAM NOBIS

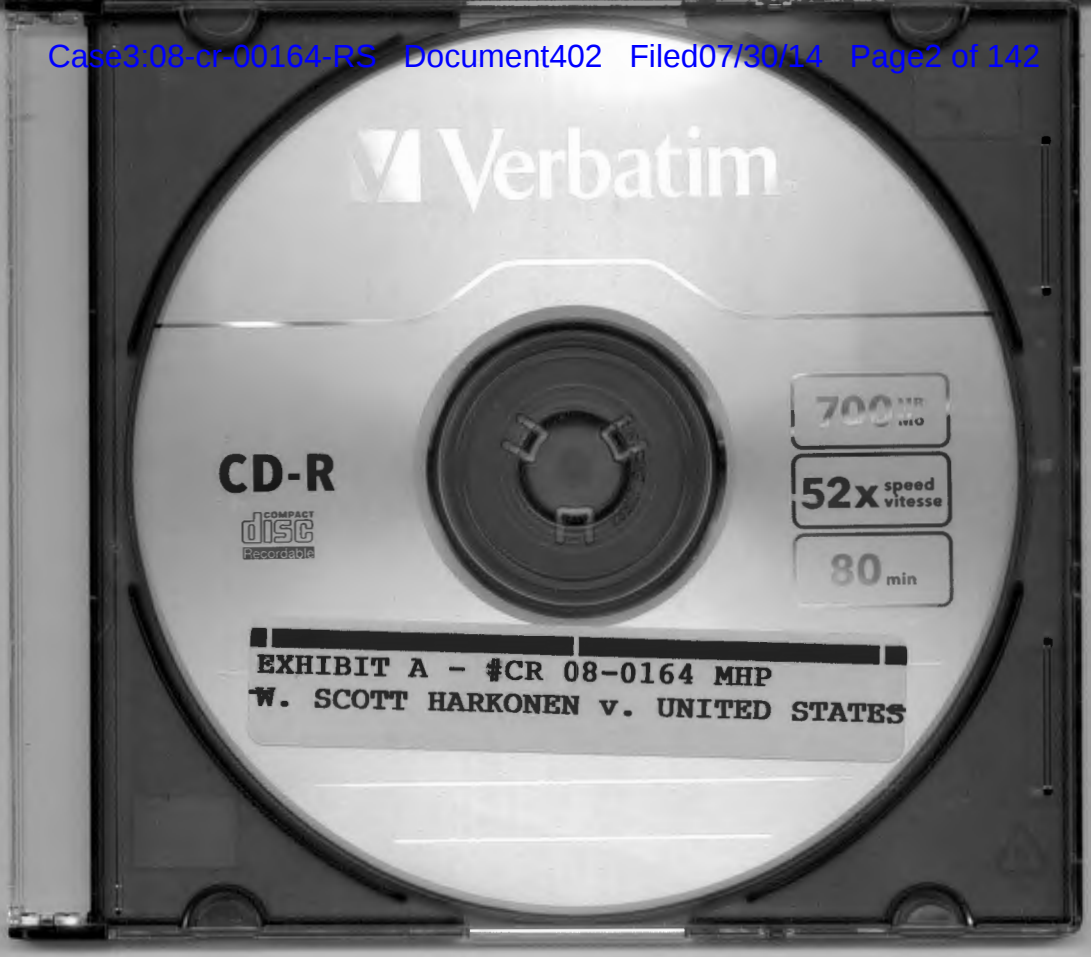
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EXHIBIT A - #CR 08-0164 MHP
W. SCOTT HARKONEN v. UNITED STATES

EXHIBIT B

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL, JUDGE

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-164 MHP SAN FRANCISCO, CALIFORNIA THURSDAY AUGUST 6, 2009 2:00 O'CLOCK P.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVE.
SAN FRANCISCO, CALIFORNIA 94102
BY: IOANA PETROU, ASSISTANT UNITED STATES ATTORNEY

AND

ALLAN GORDUS
OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, DC 20044

FURTHER APPEARANCES ON NEXT PAGE

REPORTED BY: KATHERINE WYATT, CSR 9866, RMR, RPR
OFFICIAL REPORTER - US DISTRICT COURT
COMPUTERIZED TRANSCRIPTION BY ECLIPSE

BECAUSE IF THERE IS THEN WE NEED TO PROGRAM THAT IN TO WHAT WE'RE DOING.

MR. TOPEL: YES. RIGHT.

THE COURT: BUT AS I UNDERSTAND IT THEIR CONCERN WAS ABOUT A DR. KATZ. AND IS HE ON THIS LIST NOW?

MR. TOPEL: YES.

MS. PETROU: HE IS.

MS. MOORMAN: YES.

THE COURT: OKAY. BECAUSE I THOUGHT YOU SAID "MAYER" AND "HANNON."

MR. TOPEL: I DID NOT. I STARTED NAMING NAMES, AND THEN I STOPPED NAMING NAMES, BECAUSE WE HAVEN'T MADE THE CUT AS TO WHO EXACTLY WHO THEY ARE EXCEPT TO TELL YOU THERE IS GOING TO BE ONE BIOSTATISTICIAN, ONE IPF -- ONE PULMONOLOGIST, ONE --

THE COURT: CLINICIAN AND ONE SCIENTIST.

MR. TOPEL: CLINICIAN, RIGHT.

THE COURT: BUT WHICH CATEGORY WOULD KATZ FIT INTO THEN?

MR. TOPEL: YES.

THE COURT: "YES," HE'S A CLINICIAN?

MR. TOPEL: YES, BUT HE'S MUCH MORE THAN A CLINICIAN. HE'S AN EXPERT ON THE AREAS OF HOW YOU INTERPRET RESULTS OF CLINICAL STUDIES UNDER -- UNDER -- AND HE'S ALSO A BIOSTATISTICIAN -- UNDER EVIDENCE-BASED MEDICINE.

HE'S -- ONE OF THE ISSUES THAT IS GOING TO RISE IN THIS CASE -- AND I'M NOT NECESSARILY -- ONE OF THE ISSUES IN THIS CASE IS NOT WHAT WE'RE SHOWN HERE, BUT HOW YOU INTERPRET IT.

THAT'S A HUGE ISSUE. IN FACT, IT'S THE CENTRAL ISSUE IN THIS CASE.

AND THERE ARE DIFFERENT WAYS OF DEALING WITH THIS. AND HE IS GOING TO TESTIFY ABOUT THAT.

THE COURT: OKAY. BUT DR. KATZ IS THE ONE WHO IS GOING TO TESTIFY AS WHAT YOU'VE CHARACTERIZED "THE CLINICIAN"; IS THAT CORRECT?

MS. PETROU: WELL, HE SAID IT'S HOW YOU INTERPRET CLINICAL RESULTS, WHICH IN MY MIND IS ALWAYS A BIOSTATISTICIAN.

MR. TOPEL: NO. NO. HE'S A LEADER OF A -- HE IS AN EXPERT ON A SCHOOL OF CLINICAL PRACTICE CALLED "EVIDENCE-BASED MEDICINE," WHICH IS HOW YOU INTERPRET THE RESULTS OF CLINICAL STUDIES, ONE OF THE WAYS THAT YOU DO THAT. AND THAT'S HIS AREA, AND THAT'S A DIFFERENT AREA.

THE COURT: NOW, YOU HAVE SOMEBODY ELSE WHO IS TESTIFYING AS A CLINICIAN, AS WELL?

MR. TOPEL: YES, OF COURSE. YES. I SHOULDN'T SAY "OF COURSE."

THE COURT: THEN KATZ IS LIKE AN ADDITIONAL PERSON WHO IS NOT ON THIS LIST?

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. CR 08-0164-MHP
	)	
W. SCOTT HARKONEN,	)	
	)	SAN FRANCISCO, CALIFORNIA
DEFENDANT.	)	TUESDAY
	)	AUGUST 18, 2009
	)	8:36 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: **LYDIA ZINN, CSR #9223**
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

LIVES, WHEN, IN FACT, THERE WAS NO PROOF THAT THAT WAS TRUE. IT'S A CASE ABOUT WANTING TO MAKE BELIEVE THAT A FAILED CLINICAL TRIAL WAS ACTUALLY A SUCCESS. THIS IS A CASE ABOUT A CEO AND DOCTOR WHO CARED MORE ABOUT THE HEALTH OF HIS COMPANY THAN HE DID ABOUT THE HEALTH OF PATIENTS WITH A FATAL DISEASE. THAT CEO AND DOCTOR IS THE DEFENDANT IN THIS CASE.

W. SCOTT HARKONEN.

THIS IS A SIMPLE CASE. YOU WILL NEED TO LEARN A LITTLE BIT ABOUT STATISTICS. YOU'LL NEED TO LEARN A LITTLE BIT ABOUT CLINICAL-TRIAL DESIGN IN ORDER TO UNDERSTAND WHAT HAPPENED; BUT IT'S NOT A CASE ABOUT STATISTICS, AND IT'S NOT A CASE ABOUT CLINICAL TRIALS OR TRIAL DESIGN. THIS IS REALLY A CASE ABOUT FRAUD, AND IT'S REALLY A CASE ABOUT CHOICES: THE DEFENDANT'S CHOICES.

DR. HARKONEN BUILT HIS COMPANY ON THE SALES OF ONE DRUG: ACTIMMUNE; A DRUG THAT COSTS $50,000 PER YEAR PER PATIENT.

AND IN AUGUST OF 2002 HE RECEIVED THE RESULTS FROM A CLINICAL TRIAL; A TRIAL THAT HAD FAILED. IT WAS VERY CLEAR THAT THE TRIAL HAD FAILED. DR. HARKONEN KNEW IT FAILED. HE WAS TOLD IT FAILED BY PEOPLE IN HIS COMPANY, OUTSIDE OF HIS COMPANY, AND BY F.D.A. -- THE FOOD AND DRUG ADMINISTRATION.

AND DESPITE KNOWING THIS, AND INSTEAD OF PUTTING OUT A TRIAL -- EXCUSE ME -- INSTEAD OF PUTTING OUT A PRESS RELEASE THAT CLEARLY SAID, HEADLINE, "FAILED TRIAL," DR. HARKONEN CHOSE

PULMONARY ADVISORS FOR THE F.D.A., AND THEY OVERRULED DR. WALTON. THEY SAID DR. HARKONEN AND INTERMUNE ARE CORRECT IN THE WAY THEY WANT TO DO IT. THEY USED POLITE LANGUAGE, BUT THE BOTTOM LINE IS INTERMUNE PREVAILED OVER DR. WALTON, AND THE STUDY PROCEEDED. AND THIS HAD TREMENDOUS IMPACT DOWN THE ROAD, BECAUSE DR. WALTON HELD A GRUDGE. AND WHEN THE STUDY RESULTS CAME OUT, HE WAS QUITE HOSTILE TOWARD INTERMUNE.

NOW, AS WE'VE SAID EARLIER, THIS WAS WHAT IS CALLED A GOLD-PLATED DOUBLE-BLIND PLACEBO-CONTROLLED PHASE III STUDY. THAT MEANS, LADIES AND GENTLEMEN, THAT YOU CAN'T DO IT BETTER THAN THIS. HALF THE PEOPLE ARE ON THE MEDICINE. HALF THE PEOPLE ARE ON IS SUGAR PILLS, BUT NOBODY KNOWS WHO'S ON WHAT. IT'S A DOUBLE-BLIND. AND THAT PREVENTS ANYBODY FROM FIDDLING WITH THE NUMBERS OR INTERFERING WITH THE INTEGRITY OF THE RESULTS. IT WAS CONDUCTED WITH STRICT COMPLIANCE TO ALL F.D.A. RULES. AND THE DATA IS CONSIDERED ACCURATE AND TOTALLY RELIABLE.

THE DISPUTE IN THIS CASE -- AND THIS IS ANOTHER CENTRAL POINT OF THIS WHOLE CASE. THE DISPUTE IN THIS CASE IS NOT ABOUT THE UNDERLYING NUMBERS; IT'S ABOUT HOW YOU INTERPRET THEM.

AND THE F.D.A. AND ITS ALLIES BRING A CERTAIN STATISTICAL METHODOLOGY TO BEAR, WHICH, AS I SAID BEFORE, IS BOTH SCIENTIFICALLY FLAWED, CONTROVERSIAL, AND NOT MANDATORY WHATSOEVER; AND DR. HARKONEN AND THE OTHER EXPERTS THAT YOU

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. CR 08-0164-MHP
	)	
W. SCOTT HARKONEN,	)	
	)	SAN FRANCISCO, CALIFORNIA
DEFENDANT.	)	TUESDAY
	)	SEPTEMBER 15, 2009
	)	8:30 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

CHART.

THE COURT: YES, OKAY. WELL, WE WILL SEE.

MR. TOPEL: ALL RIGHT. YOUR HONOR, AGAIN, I APOLOGIZE FOR MY SHORTNESS.

THE COURT: YES. YES.

MR. TOPEL: NOT SOMETHING THAT -- I GOT TO GET OUT OF HERE.

THE COURT: TAKE A PILL. TAKE SOMETHING.

MR. TOPEL: WHATEVER, RIGHT.

THE COURT: A PLACEBO.

MR. TOPEL: NO, LET'S GO EAT LUNCH.

THE COURT: GO EAT LUNCH.

MS. PETROU: EXACTLY.

THE COURT: OKAY. SO WE WILL SEE YOU TOMORROW MORNING AT 8:30. I'LL TRY TO BE HERE A LITTLE BIT BEFORE, AND WE CAN TAKE UP A COUPLE OF THESE MATTERS BUT --

MS. PETROU: AND WE WILL PREPARE THAT EXHIBIT THAT IT WAS JUST CERTAIN OF THE SLIDES AND HAVE THAT READY AND UPDATE YOUR BINDERS AND DEFENSE COUNSEL AND EVERYBODY.

THE COURT: ALL RIGHT. FINE.

MR. TOPEL, ARE YOU, IN FACT, CALLING DR. MAYER?

MR. TOPEL: YES.

THE COURT: OKAY. BECAUSE IT SOUNDED AS IF YOU MAY BE REVISITING WHAT YOU ARE GOING TO BE DOING, AND SO FORTH. I DIDN'T WANT TO SPEND MY TIME GOING OVER THIS IF YOU ARE NOT

CALLING HIM.

MR. TOPEL: NO, WE ABSOLUTELY ARE CALLING HIM. NO QUESTION ABOUT IT.

THE COURT: OKAY.

(THEREUPON, THIS TRIAL WAS CONTINUED UNTIL WEDNESDAY, SEPTEMBER 16, 2009 AT 8:30 O'CLOCK A.M.)

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. CR 08-0164-MHP
	)	
W. SCOTT HARKONEN,	)	
	)	SAN FRANCISCO, CALIFORNIA
DEFENDANT.	)	WEDNESIDAY
	)	SEPTEMBER 16, 2009
	)	8:30 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: **LYDIA ZINN, CSR #9223**
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

EXISTED BECAUSE YOU'RE GOING TO -- I'M GOING TO ARGUE TO THE JURY:

"THE FIRST QUESTION YOU HAVE TO GET TO BEFORE YOU GET TO INTENT, BEFORE YOU GET TO ANYTHING ELSE, MATERIALITY OR WHAT HAVE YOU, IS: WAS THIS FALSE? WAS THERE -- HAVE THEY PROVEN BEYOND A REASONABLE DOUBT THAT THERE WAS NO MORTALITY BENEFIT?"

AND WE'RE ENTITLED TO DO THAT. THAT'S THE FUNDAMENTAL, CONSTITUTIONAL, PIVOTAL ISSUE AND SUBSTANTIVE ISSUE IN THIS CASE.

AND IF DR. MAYER SAYS UNDER ANY THEORY THIS IS TRUE, AND BASICALLY THAT FLEMING IS WRONG, WHICH IS WHAT HE'S GOING TO SAY, HE IS ENTITLED TO SAY THAT.

THE CAST YOU'RE PUTTING ON IT, FRANKLY, IS VERY CONFUSING TO ME, BECAUSE --

THE COURT: OH, I THINK IT'S EVEN MORE CONFUSING WHEN YOU THROW IN ALL OF THE OTHER OPTIONS --

MR. TOPEL: BUT IT DOESN'T --

THE COURT: -- THAT MIGHT HAVE BEEN AVAILABLE OUT THERE.

MR. TOPEL: IT'S NOT A QUESTION OF CONFUSION. AND, IN FACT, THERE'S CASE LAW THAT IS SOMEWHAT ANALOGOUS TO THIS, THAT, FIRST OF ALL, IT'S NOT -- RIGHT NOW IT'S VERY CONFUSING. I THINK AFTER DR. MAYER TESTIFIES IT'S GOING TO BE FAR MORE CLEAR ABOUT WHAT IS GOING ON.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. CR 08-0164-MHP
	)	
W. SCOTT HARKONEN,	)	
	)	SAN FRANCISCO, CALIFORNIA
DEFENDANT.	)	FRIDAY
	)	SEPTEMBER 18, 2009
	)	8:38 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

THE COURT: ALL RIGHT. PLEASE BE SEATED.

AND, YES, MR. TOPEL, YOUR NEXT WITNESS.

MR. TOPEL: YES, YOUR HONOR. AT THIS TIME THE DEFENSE WILL REST. WE ARE PREPARED TO ARGUE THIS CASE TO THE JURY.

THE COURT: OKAY. BUT NOT TODAY.

MR. TOPEL: I'LL DO IT TODAY. I DON'T KNOW IF THEY WANT TO HEAR IT TODAY.

NO, I GOT A DIRTY LOOK.

THE COURT: CAN YOU ARGUE YOUR CASE IN FIVE MINUTES?

MR. TOPEL: NO, WHATEVER. NOT TODAY. NOT TODAY. NOT TODAY.

THE COURT: DO YOU INTEND TO CALL ANY REBUTTAL WITNESSES?

MS. PETROU: NO, YOUR HONOR.

THE COURT: OKAY. SUBJECT TO CLEANING UP ANY EXHIBITS THAT YOU NEED TO CHECK AND MAKE SURE WITH MR. BOWSER THAT EVERY EXHIBIT THAT YOU THINK IS IN IS, IN FACT, IN, AND GETS STRAIGHTENED OUT WITH HIM, AND ANY MATTERS YOU'RE GOING TO TAKE UP WITH ME.

THAT MEANS THAT WE'VE COMPLETED THE EVIDENTIARY PORTION OF THE TRIAL.

WOW.

JUROR UMANI: WOW.

THE COURT: YOU WANTED MORE?

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. CR 08-0164-MHP
	)	
W. SCOTT HARKONEN,	)	
	)	SAN FRANCISCO, CALIFORNIA
DEFENDANT.	)	WEDNESDAY
	)	SEPTEMBER 23, 2009
	)	8:35 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

GET A REAL SENSE OF THE RESULTS.

ALSO, THEIR OPINIONS NEVER DID CHANGE. THERE'S NO EVIDENCE IN THIS CASE THAT THEIR OPINIONS EVER CHANGED.

SO LET'S SEE WHAT OPINIONS -- OR WHAT THEY TOLD THE DEFENDANT ON THIS CALL.

NOW, DR. WALTON SPOKE FOR THE F.D.A. ON THIS CALL. AND HE COULD NOT BE CLEARER THAT THE SUBGROUP ANALYSES THAT THEY HAD SENT TO F.D.A., WHILE INTERESTING, DIDN'T PROVE ANYTHING. THERE WAS NO WAY TO KNOW IF THESE RESULTS WERE REAL, OR SIMPLY DUE TO CHANCE.

AND THIS IS WHAT HE SAYS. HE DESCRIBED THE DATA AS SHOWING A VERY SUGGESTIVE AND OPTIMISTIC TREND; BUT THAT, AS THIS WAS NOT THE PRIMARY ENDPOINT, THE DATA WOULD NOT CARRY THE DAY, NO MATTER WHAT ONE DOES.

HE WENT ON TO EXPLAIN THIS MORE.

IN REGARDS TO GIPF-001, DR. WALTON STATED THAT -- OR EXCUSE ME. LET ME START FROM THE BEGINNING, RIGHT HERE -- INDICATED THAT THE GIPF-001 FAILED TO DEMONSTRATE EFFICACY ON ITS PRIMARY ENDPOINT.

IN REGARDS TO GIPF-001, DR. WALTON STATED THAT BECAUSE OF THE PHYSIOLOGIC MEASUREMENTS -- OR BECAUSE THE PHYSIOLOGIC MEASUREMENTS DID NOT SHOW ANY APPARENT TREATMENT EFFECT, THE DECREASE IN MORTALITY, IN HIS OPINION, COULD BE CONSIDERED ALMOST AN ANOMALOUS FINDING, IN THE FACE OF NO EFFECT ON PULMONARY FUNCTION, AND SO WARRANTS EXTRA CAUTION.

REPLY? GO UP TO THE TOP. GO UP ONE.

"THE FAX NUMBER I HAVE FOR YOU DIDN'T WORK, BUT I WAS ABLE TO GET AN ELECTRONIC COPY FROM OUR WEBSITE. IT'S ATTACHED."

OKAY. NOW, LET'S GO TO D708.

OH, THIS IS IT? COME ON. GIVE ME THE NEXT PAGE, PLEASE.

ALL RIGHT. NOW, HERE IT IS, RIGHT IN THE SECOND PAGE. AND GUESS WHAT? AND IF YOU LOOK AT THESE NUMBERS ON THE BOTTOM, "FLEM," THEY ARE ABSOLUTELY CONSECUTIVE.

OKAY. HERE'S THE NEXT PAGE. AND THIS IS OBVIOUSLY A PRESS RELEASE THAT CAME FROM A WEBSITE, BECAUSE ANYBODY WHO HAS HAD -- I GUESS ALL OF US HAVE NOW HAD ENOUGH EXPERIENCE TO KNOW THAT WHEN YOU SEE THIS KIND OF STUFF YOU KNOW IT'S FROM A WEBSITE.

AND, OF COURSE, IF YOU LOOKED AT THE ACTUAL PRESS RELEASE -- AND I JUST HAPPEN TO HAVE A COPY WITH ME -- THE ORIGINAL PRESS RELEASE DOESN'T HAVE ANYTHING LIKE THAT ON IT WHATSOEVER.

WHAT OUR FRIEND, DR. CRAGER, OUR EXPERT -- AND, LADIES AND GENTLEMEN, MAYBE THIS IS A GOOD TIME FOR ME TO REMIND YOU THAT WAY BACK AT THE BEGINNING OF THE CASE, WHEN WE DIDN'T REALLY KNOW WHAT THE EVIDENCE IN THIS CASE, HOW IT WAS GOING TO BE, I TOLD YOU THAT WE WERE GOING TO CALL EXPERTS IN THIS CASE.

IT TURNED OUT THAT OUR EXPERTS CAME IN THE GOVERNMENT'S CASE: DR. CRAGER, AND BY HIS ABSENCE, DR. PENNINGTON AND DR. BRADFORD, AND CERTAINLY AND CERTAINLY DR. PORTER. AND, OF COURSE, THE DEFENSE, AS YOU WELL KNOW -- WELL, IN ANY EVENT, HERE IS -- HERE IS THE PRESS RELEASE THAT WAS SENT TO MR. FLEMING OR DR. FLEMING ON THE 30TH.

GO BACK TO THE E-MAIL, PLEASE. GO BACK TO THE E-MAIL.

GO UP TO THE E-MAIL. ALL RIGHT. AUGUST 30TH, 2002, HE GETS -- HE GETS THE PRESS RELEASE. WHY DID HE LIE?

WHY DID HE COME IN HERE AND SAY:

"I GOT IT ON THE 4TH, AND I WAS SO UPSET I STAYED UP ALL NIGHT"?

WHY? BECAUSE HE'S AN EXAGGERATOR. HE'S ATTEMPTING TO SELF-PROMOTE HIS OWN POINT OF VIEW TO MAKE IT MORE DRAMATIC. BUT THE FACT THAT HE LIED TO YOU -- AND IT'S VERY CLEAR HE LIED TO YOU -- COLORS HOW YOU SHOULD LOOK AT THE REST OF HIS TESTIMONY.

HE ALSO MADE THREE EGREGIOUS MISSTATEMENTS IN HIS LETTER WHEN HE WAS CRITICIZING THE AUGUST 28TH PRESS RELEASE. FIRST HE SAID THAT DEATHS WERE LEFT OUT IN THE ACTUAL NUMBERS; THAT HE SAYS THAT JULY 26 WAS NOT THE CUTOFF.

YOU HAD FIVE WITNESSES, AND MAYBE TEN EXHIBITS, THAT TALKED ABOUT JULY 26 BEING THE CUTOFF.

LOOK AT THE SOP, THE FINAL SOP. IF YOU LOOK IN THE TESTIMONY OF CRAGER AND THE TESTIMONY OF PORTER AND THE OTHER

NOTES. A LOT OF YOU TOOK NOTES. LOOK AT THE ACTUAL EXHIBITS. WE'VE HAD OVER TWENTY WITNESSES. WE'VE HAD OVER 190 EXHIBITS.

THE EVIDENCE HAS BEEN BEFORE YOU. THE EVIDENCE SHOWS WITHOUT QUESTION THAT THE TRIAL FAILED. AND, OF COURSE -- AND, AGAIN, THERE'S NO CONTROVERSY ABOUT THIS -- THERE IS GREAT VALUE IN POST HOC ANALYSES. THERE'S GREAT VALUE IN LOOKING AT DATA AND SEEING WHAT MIGHT BE THERE.

AND, IN FACT, THAT'S WHAT HAPPENED. AND, YOU KNOW, SOMETHING THAT GOT LEFT OUT OF DEFENSE COUNSEL'S CLOSING WAS WITHIN A MATTER OF WEEKS, IF NOT DAYS, THE NEXT PHASE III TRIAL WAS BEING DESIGNED. THEY WERE DOING WITH THE DATA EXACTLY WHAT DR. CRAGER THOUGHT THE WHOLE PURPOSE OF THE POST HOC ANALYSES WAS.

HE THOUGHT WHOLE PURPOSE WAS:

"OF COURSE WE'RE GOING TO HAVE TO DO ANOTHER TRIAL BECAUSE WE HAVEN'T PROVEN ANYTHING."

AND VERY SOON THEREAFTER THEY START DESIGNING THE TRIAL. AND THEY KEEP WORKING ON DESIGNING THAT TRIAL.

WHY WOULD YOU DO ANOTHER TRIAL IF THE RESULTS WERE CLEAR? WHY WOULD YOU DO ANOTHER TRIAL IF THE RESULTS HAD BEEN DEMONSTRATED?

AND, YOU KNOW, LET'S TALK ABOUT DR. CRAGER FOR A MINUTE OR TWO.

THE EVIDENCE IS CLEAR THAT DR. CRAGER ONLY CORRECTED A P-VALUE IN THE PRESS RELEASE BECAUSE HE HAPPENED TO BE IN THE

PAGES 1 - 60

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. CR 08-164 MHP
	)	
W. SCOTT HARKONEN,	)	SAN FRANCISCO, CALIFORNIA
	)	FRIDAY, FEBRUARY 19, 2010
DEFENDANT.	)	
	)	

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF:

JOSEPH P. RUSSONIELLO
UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE
SAN FRANCISCO, CALIFORNIA 94102

BY: **IOANA PETROU**
ASSISTANT UNITED STATES ATTORNEY

DOJ OFFICE OF CONSUMER LITIGATION
LIBERTY SQUARE BUILDING
450 FIFTH STREET, NW
SIXTH FLOOR SOUTH
WASHINGTON, DC 20001

BY: **ALLAN GORDUS**
TRIAL ATTORNEY

(FURTHER APPEARANCES ON FOLLOWING PAGE)

REPORTED BY: JOAN MARIE COLUMBINI, CSR #5435, RPR
OFFICIAL COURT REPORTER, U.S. DISTRICT COURT

EVERY WITNESS IN THIS CASE, INCLUDING WALTON WHO SAW THE RESULTS AS PROMISING AND INTERESTING, EVERYBODY AGREED, THERE WAS SOMETHING GOING ON.

THE QUESTION THAT BECAME THE FIGHT IN THIS COURTROOM IS: TO WHAT DEGREE CAN ONE SAY SOMETHING WAS GOING ON? THE FACT IT DIDN'T MEET ITS PRIMARY ENDPOINT ONLY MEANT IT WASN'T GOING TO GET ON LABEL. THAT IS NOT THE WHOLE WORLD. THAT'S A VERY SMALL SLICE OF THE WHOLE WORLD.

AGAIN, HAD THE GOVERNMENT WANTED TO PROVE THAT'S THE ONLY WAY YOU CAN GO -- AND THE ANSWER ISN'T WE HAVE TO PROVE ANYTHING BECAUSE WE DIDN'T HAVE THE BURDEN OF PROOF HERE. THEY COULD HAVE CALLED EXPERT TESTIMONY TO TESTIFY ABOUT THESE AREAS. THEY CHOSE NOT TO, VERY DELIBERATELY CHOSE NOT TO, AND HAVE TO STAND ON WHAT THEY HAVE IN THE RECORD OF THIS CASE.

THE COURT: WELL, DOES THE PRESS RELEASE SAY ANYTHING ABOUT PRIMARY ENDPOINT AND THE FACT THE PRIMARY ENDPOINT WAS MISSED?

MR. TOPEL: YES. IT SAYS IT TWICE.

THE COURT: AND DOES THAT MATTER?

MR. TOPEL: YES, IT DOES MATTER. IT MATTERS BECAUSE YOU'RE TALKING TO A COMMUNITY, AND YOU WANT TO POINT OUT BOTH THE POSITIVE AND THE NEGATIVE, AND THEY SAID IT TWICE IN THE PRESS RELEASE, THAT THEY HADN'T MET THE PRIMARY ENDPOINT.

NOW, THE GOVERNMENT ARGUED AT SOME LENGTH IN THIS CASE THAT SOMEHOW THERE WAS A RULE THAT YOU HAD TO SAY YOU ALSO

Pages 1 - 172

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL, JUDGE

UNITED STATES OF AMERICA, Plaintiff,	)	
v.	)	NO. CR 08-00164 MHP
W. SCOTT HARKONEN, Defendant.	)	

San Francisco, California
Wednesday, April 13, 2011

TRANSCRIPT OF SENTENCING PROCEEDINGS

APPEARANCES:

For Plaintiff:

MELINDA L. HAAG, ESQ.
United States Attorney
450 Golden Gate Avenue
San Francisco, California 94102

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(Appearances continued on following page.)

Reported By: Leo T. Mankiewicz, CSR 5297, RMR, CRR

That's not correct. The defendant has cited one case from the Atlantic Reporter for that proposition. In actuality, your Honor, the case law is far from clear that these documents, which are riddled with hearsay, would come in at all or would come in as admissions of a party opponent.

There is a considerable body of case law that says people who work for the government, and who do things like make decisions about drugs and prescribing things, can't bind the sovereign; because clearly, there, there are going to be a large number of people who are going to take inconsistent positions in the government, and so that's the law.

So I do not think that these documents that the defendant points to would have been admissible, and even if they had been admissible, I don't see how they come in as admissions of a party opponent.

The second thing, which counsel downplays, is the fact that he was prepared, or -- the defendant was prepared, before trial, to put on two experts to say exactly what the defendant says these documents say; and I don't see how the defendant now believes that these documents led them to believe for the first time that there might be doctors in the VA who weren't persuaded by the press release. Mr. Harkonen -- Dr. Harkonen had two experts who were prepared, Dr. Zibrak and -- I can't recall the other expert's name, who were prepared to say that doctors don't rely on press releases in

making prescribing decisions.

The defendant knew that this defense was available, chose not to pursue it. The defense at trial was that the press release was true and that it was important, and that the defendant needed to get this information out because people were dying.

I don't have anything more, your Honor, unless you have specific questions for the government.

THE COURT: Anything further?

MR. HADDAD: I do have a few responses.

THE COURT: Very briefly, yes.

MR. HADDAD: First, on the very first point, about counsel at trial having admitted materiality, that did not happen. What counsel admitted was that the facts, the data, were important. This is the same critical overarching point that we started with this morning. There is no admission at trial that the conclusions that the company drew could have affected the judgment of doctors.

Second, in terms of proving materiality through the patients, this is a money and property offense. The only way the patients get the drug is if the doctors approve it, and the doctors do sit down, and any doctor who is following his or her professional obligations is going to sit down and talk about all the data, talk about the patient's medical condition, go through whatever review processes apply. That's the process.

case. I mean, I didn't -- apparently, the doctors, there were some doctors in that case who had prescribed medication or the plaintiffs who were bringing the lawsuit, and apparently, they were not contacted by the government, or anyone in this case, but in any event, there was really just no way that the plaintiffs in that case, despite, I think, three complaints, you know, allowed to amend two or three times, could come up with the kind of connection with the victims, if you will, who were prescribed medication by their doctors, because the doctors were the ones who were ultimately making the decision.

MR. HADDAD: And I would just add, back on the burden of proof, you can't just accept the declarations at face value or the letters at face value, because they have L.K.M.'s declaration saying, "I suffered side effects," but when you go through the medical records, it's not there, and Dr. Zibrak two declarations, which cover the gamut of the medical records, detail all of the records and the absence of side effects that were reported in the medical records, and he also explains more broadly that as compared to the alternative treatments, which were also very expensive, Actimmune was far less harmful and toxic to the body. The other treatments that were being given were high-dose steroids, which are devastating in terms of their side effects; cytotoxic drugs, which are essentially cancer drugs that are, again, extremely toxic and hard on the body, causing all kinds of side effects.

EXHIBIT C

Nos. 11-10209, 11-10242

IN THE UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellee/Cross-Appellant,

v.

W. SCOTT HARKONEN,

Defendant-Appellant/Cross-Appellee.

BRIEF FOR THE UNITED STATES AS APPELLEE/CROSS-APPELLANT

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
NO. CR-08-00164-MP

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March 30, 2012

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BRIEF FOR THE UNITED STATES AS APPELLEE/CROSS-APPELLANT

INTRODUCTION

This is not a case about criminalizing differing but sincerely held scientific opinions. This is a case about defendant's knowing false and fraudulent statements - statements the jury found were made with the intent to defraud – in a press release describing the results of a clinical trial of a drug that was defendant's company's principal source of revenue. Nothing in the First or Fifth Amendment precludes such a prosecution.

As the evidence showed beyond a reasonable doubt, although the clinical trial indisputably failed to meet all of its own pre-specified objectives, it was presented to the public by defendant as a success. The press release stated that the

"data demonstrate[d] [a] survival benefit" and "reduces mortality by 70% in patients with mild to moderate disease." Although the release included data that appeared to support the conclusion that these results were reliable, it purposefully omitted data showing they were not.

Defendant, the architect of the misleading release, issued it despite the fact that he was told repeatedly before it was issued that the clinical trial had failed to meet any of its own pre-determined objectives, and that no firm conclusions about a survival benefit could be drawn from the data. In a departure from his company's normal practice, defendant prevented his technical staff, including the doctors and the biostatistician at InterMune most involved in the trial and the analyses of its results, from reviewing the release prior to its publication. When the press release was issued, it was the only publicly available material about the results, and defendant knew that the press release would be used by his company's salesforce and others to generate additional sales.

This Court should affirm defendant's conviction, but reverse defendant's sentence.

JURISDICTION, TIMELINESS, AND BAIL STATUS

The district court had jurisdiction under 18 U.S.C. § 3231. The district court entered its order of judgment and commitment on April 18, 2011, and an

amended order on May 25, 2011. ER 5, 13.[1] Defendant filed timely notices of appeal, and the government timely filed a notice of appeal from Harkonen's sentence. ER 1, 10; CR 378; SER 5616; *see* Fed. R. App. P. 4(b). This Court has jurisdiction under 28 U.S.C. § 1291. Defendant was sentenced to probation, with six months' home confinement. ER 7.

ISSUES PRESENTED

I. Whether this Court should affirm defendant's wire fraud conviction for knowingly making false and fraudulent statements in a press release targeted to doctors and patients regarding the results of a clinical trial to determine the efficacy of Actimmune, his company's principal source of revenue.

II. Whether the First Amendment bars a criminal prosecution of false statements made with an intent to defraud whenever they concern scientific matters.

III. Whether defendant had fair notice that misrepresenting the clinical trial results of his company's principal source of revenue in a press release could serve as the basis for a wire fraud conviction.

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[1] "CR" refers to the district court criminal docket, "ER" to appellant's excerpts of record, "AOB" to appellant's opening brief, "SER" to government's supplemental excerpts of record, and "PSR" to the presentence report filed under seal in accordance with Circuit Rule 30-1.10.

IV. Whether the district court erred by not instructing the jury on a good faith or puffing defense, where, consistent with this Court's controlling law, the court told the jury that it had to find intent to defraud and defendant has not challenged the sufficiency of that instruction.

V. Whether the district court abused its discretion by denying the defendant's motion for a new trial based on his claims of a *Brady* violation and newly discovered evidence.

VI. Whether the district court erred as a matter of law in calculating defendant's Sentencing Guidelines range by (a) failing to consider defendant's intended loss, after rejecting the government's actual loss calculations; and (b) refusing to apply the vulnerable victim enhancement under U.S.S.G. § 3A1.1(b)(1).

STATEMENT OF THE CASE

On March 18, 2008, a federal grand jury indicted W. Scott Harkonen for wire fraud, in violation of 18 U.S.C. § 1343, and misbranding, in violation of 21 U.S.C. §§ 331(k), 333(a)(2), 352(a). CR 1.

Prior to trial, defendant sought to dismiss the indictment, or to exclude evidence on First Amendment grounds. CR 88; ER 2891. The district court denied that motion in a written order. CR 124; ER 144-62.

On September 29, 2009, a jury found defendant guilty of wire fraud, but not guilty of misbranding. CR 1, 240. The district court denied Harkonen's post-trial motions in two written orders. CR 268, 369; ER 19-36, 36-66.

On April 13, 2011, the district court sentenced Harkonen to three years' probation, six months' home detention, community service, and a $20,000 fine. SER 3754-55; CR 365.

STATEMENT OF THE FACTS

A. InterMune and Actimmune

From February 1998 through approximately June 30, 2003, W. Scott Harkonen was the Chief Executive Officer of InterMune, a biopharmaceutical company that developed, marketed, and sold drugs for lung and liver diseases. ER 2304. As CEO, defendant directed InterMune's operations, including research, marketing, and investor relations. Defendant was also a member of InterMune's Board of Directors from February 1998 through September 2003, and Chairman of the Board starting in January 2000. ER 2304.

InterMune's revenue came almost entirely from "interferon gamma-1b," sold under the brand name "Actimmune." ER 2305; SER 91. Although the United States Food and Drug Administration ("FDA") had approved Actimmune for the treatment of two rare pediatric diseases, SER 146, 150-53, Actimmune's

main market was for a fatal disease called idiopathic pulmonary fibrosis ("IPF") that causes a person's lungs to gradually fill up with scar tissue. ER 37, 2305. That scar tissue eventually prevents the lungs from working, resulting in slow suffocation. ER 37, 2008. Death usually follows within two to five years after diagnosis. *Id.* There are approximately 200,000 individuals in the United States who suffer from the disease, and 50,000 new cases are diagnosed each year. ER 37. To date, there is no effective treatment or cure for IPF. ER 2307.

Because of the lack of treatment options for this fatal disease, a small 1999 European study of 18 individuals (the "Ziesche study") suggesting that Actimmune might help treating IPF generated significant interest in the drug.[2] ER 37; SER 617-20. The cost of Actimmune for one IPF patient for one year was approximately $50,000. SER 1040, 2464. As defendant said during a July 2001 company-wide national sales meeting, "the market opportunity here is 2 and a half billion . . . . basically, it's simple math. . . . There is no reason we shouldn't capture 40% of this market and turn Actimmune into a billion dollar revenue producer."[3] SER 2468-69, 5618 (Exs. 33 at 13, 34). In late 2000, InterMune

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[2] After the Ziesche study was released, questions surfaced about how that study was conducted. *See* SER 617-25.

[3] Due to their size, the government has submitted the relevant trial exhibits on a CD-ROM to the Court. At the Court's request, the government is prepared to submit additional paper copies.

started to hire sales representatives to focus on sales of Actimmune for IPF treatment. SER 2448-50, 5618 (Exs. 33 at 27-30).

B. The Clinical Trial of Actimmune for IPF

Although doctors could prescribe Actimmune for IPF, the FDA had not approved it for that use.[4] SER 146-50. In 2000, InterMune undertook a clinical trial, known as the GIPF-001 trial, to determine the efficacy of Actimmune for IPF. SER 153-54. InterMune planned to use the results, if favorable, to seek FDA approval for Actimmune to treat IPF and thereby increase its sales. SER 153-54.

Dr. Marc Walton, the FDA's Chief of the General Medicine Branch of the Division of Clinical Trial Design and Analysis, supervised the medical officer who reviewed the Actimmune GIPF-001clinical trial. SER 101-02, 154; ER 2215-25. Dr. Walton testified that Phase III clinical trials like the GIPF-001 trial are studies in which neither the patient nor his or her doctor knows whether the patient is getting the drug or a placebo. SER 122-23. Phase III clinical trials are conducted at different sites, with a principal investigator at each site. SER 118-19. The information gathered by the doctors during the clinical trial is sent to an independent contract research organization, which collects and analyzes the data

[4] FDA-approved labels state all the diseases the FDA has approved the drug to treat. SER 146, 149-50. Drugs have "off-label" uses if used by physicians to treat a disease not on those labels. *Id.*

before giving it to the company. SER 118-19, 124-26. The company then discusses the results with the FDA. SER 139.

Before undertaking a Phase III trial, researchers set forth a detailed written clinical trial protocol, which includes, among other things, the trial's objectives, and how to analyze the data collected to determine whether these objectives have been met. SER 120, 131-32, 5618 (Ex. 281). It is not uncommon for the protocol to change after a clinical trial begins, but a final written protocol must be in place before the clinical trial's data are made available to the researchers. SER 121-22, 132. The predetermination of the clinical trial's objectives (or "endpoints") as well as the criteria for how the data will be analyzed (the "Statistical Analysis Plan") is crucial for the integrity of the clinical trial. SER 130-33.

The principal objective that a clinical trial is designed to measure is called the "primary efficacy endpoint." SER 133-37. There is typically only one primary endpoint per trial, and the trial is carefully designed to assess that endpoint. SER 133-37. A clinical trial may include other less important "secondary" endpoints. SER 135. Those secondary endpoints are ranked, beginning with the most informative and most likely to succeed. SER 138. A third category, tertiary or exploratory endpoints, are given less weight and are not intended as a basis for drawing any firm conclusions. SER 135.

By pre-specifying what the clinical trial is intended to measure and how it will be measured, researchers preclude themselves from manipulating the data in search of favorable results. SER 132. As Dr. Walton testified, "[i]t's well-understood if one can look at the data and then pick out which parts of the data we would like to analyze and in which way, we can always find something in the data that will look positive." *Id.*; *see also* SER 442, 1958.

InterMune created a protocol or Statistical Analysis Plan ("SAP") for the GIPF-001 trial in 2000, and made several amendments to it prior to the revealing of the data on June 26, 2002. SER 5618 (Exs. 274-81). In all the versions of the SAP, however, the GIPF-001 trial had one primary endpoint: progression-free survival or patients living without any worsening of their lung capacity. *Id.* Progression of IPF was defined as either a specific, measurable decrease in Forced Vital Capacity ("FVC"), a measure of lung function,[5] a specific, measurable increase in the A-a gradient (another measure of lung function), or the death of the patient. *Id.*; ER 2276. In its final form, the SAP identified nine secondary endpoints, listed in order of clinical relevance, and eight tertiary endpoints. ER 2276-77. The seventh-ranked secondary endpoint for the clinical trial was

[5] FVC measures lung function as a percentage of normal lung function; *i.e.*, the higher the percentage, the better the function. ER 47.

survival, also referred to as mortality (*i.e.*, patients not dying while taking the medicine). ER 2277. Survival was ranked seventh in part based on concerns that there would not be enough deaths for a meaningful statistical analysis. SER 429-30. In addition, the SAP strictly defined how the data would be analyzed to determine whether each endpoint had been met. SER 425-30, 1958-59; ER 2281-94. Significantly, the SAP did not allow for analyzing the data by subgroups based upon the patients' FVC. SER 428.

The GIPF-001 trial involved 330 patients – 162 treated with Actimmune, 168 receiving a placebo – located at 58 separate facilities throughout the United States. ER 41. Dr. Ganesh Raghu, a board certified pulmonologist, was the chair of the Steering Committee responsible for the design of the clinical trial, and also a principal investigator. SER 626-27, 629-30. The Data Monitoring Committee ("DMC"),[6] an external group of scientists whose principal role was to safeguard the interests of patients who were enrolled in the clinical trial, was chaired by Professor Thomas Fleming. SER 416-17. Fleming had received his Ph.D. in statistics from the University of Maryland in 1976, had worked for seven years at the Mayo Clinic as a consultant in the Department of Epidemiology and Statistics, and had been a professor of biostatistics at the University of Washington in Seattle

[6] The DMC is also sometimes called the Data Safety Monitoring Board.

for 25 years. SER 407-16; ER 2226-48. Fleming testified that he had overseen more than 200 clinical trials, and that he had published more than 200 articles and several books about biostatistics. SER 411-14. The Committee monitored the course of the trial, and how the data were collected regarding the safety and efficacy of Actimmune. SER 416-21.

C. Defendant's Predictions of Increased Revenues

Before the clinical trial ended, Harkonen worked with InterMune's sales and marketing staff to project the impact of the trial results on Actimmune's sales. SER 2488-96. Defendant asked David Cory, Senior Vice President of Sales and Marketing, to present these projections to InterMune's Board of Directors, and approved that presentation in advance. SER 2488. The presentation addressed three different scenarios: (1) if the trial results hit both the primary endpoint and several secondary endpoints, revenue could be expected to increase from approximately $90 million in 2002 to $180 million in 2003, $300 million in 2004, and $750 million in 2007; (2) if the results were equivocal, for example, the primary endpoint had failed, but one of the secondary endpoints had been hit, then revenues could be expected to increase from approximately $90 million in 2002 to $130 million in 2003, $160 million in 2004, and $450 million in 2007; and (3) if neither the primary nor secondary endpoints were met, InterMune could expect a

"flat revenue trend," with revenues remaining solidly less than $100 million. SER 2492-96, 5618 (Ex. 31 at 11).

D. The Study Fails; Defendant Asks For Additional Analysis

On August 16, 2002, Dr. Michael Crager, InterMune's chief biostatistician, received the results from the GIPF-001 trial, and learned that the primary and all nine secondary endpoints had failed. SER 1972-73, 448, 450. As Dr. Fleming testified, "the results were entirely consistent with [Actimmune having] *no* effect." SER 448 (emphasis added). On or around August 16, 2002, defendant called Stephen Rosenfield, InterMune's general counsel, to tell him "that the data really wasn't looking very good." SER 2862-63. By InterMune's own internal criteria, this was the worst of the possible outcomes they had anticipated. SER 2492-96.

Generally, the significance of primary endpoint results is primarily expressed through the p-value, which is a number between 1 and 0. ER 43; SER 437. The lower the p-value, the greater the probability that the result reflected by the data is meaningful, and not due to chance. ER 43; SER 437-39. For example, a p-value of 0.05 indicates that the data obtained in the trial would occur by chance less than 5% of the time. ER 43; SER 438-39. As a general matter, if the p-value for the primary endpoint is less than 0.05, then the results on the primary endpoint are considered statistically significant; if greater than 0.05, the results are

generally considered unreliable and not statistically significant. SER 135, 437-38; ER 43. Here, the p-value for the GIPF-001 primary endpoint, progression-free survival time, was 0.52 – far too high to demonstrate any statistically significant correlation between Actimmune and progression-free survival. SER 590; *see also* SER 239, 448, 450, 1972-73.

A p-value can be calculated for all the results of a study, including its secondary endpoints, tertiary endpoints, and even endpoints determined through post hoc analyses – that is, analyses that are not in the SAP and are done after the data has been revealed. However, to properly interpret a p-value, it is necessary to understand the context in which each p-value was generated. SER 439. Specifically, in order to understand a particular p-value, one needs to know, among other things: (1) how many endpoints there are, because the more secondary and tertiary endpoints there are, the less statistically reliable the results for any one endpoint are likely to be ("the multiplicity effect")[7]; (2) whether the primary endpoint has failed, because secondary endpoints are dependent on the primary endpoint achieving statistical significance; and (3) whether the analysis was pre-specified. SER 439-42. Accordingly, a p-value below 0.05 for secondary, tertiary, and post-hoc endpoints may not be statistically significant,

[7] Thus, it is critical to know how many analyses were done. SER 439-40.

depending on their context. *Id.* In particular, if the primary endpoint has failed – that is, its p-value is larger than .05, then as a general matter, no definitive conclusions can be drawn from all other analyses arising out of that clinical trial, including secondary endpoints, even if they have a p-value lower than 0.05. SER 136-38, 441-42, 1959.

In looking at the results, Crager noticed a "trend" in the results suggesting a survival benefit, the seventh of the secondary endpoints, but concluded that that finding too was not statistically significant. SER 1972-73. Crager reported this fact to defendant and to Dr. Jim Pennington, InterMune's Executive Vice President of Medical and Scientific Affairs, telling them that there was "no evidence of an effect on the primary efficacy endpoint, but that there was a trend in the survival data" which, he concluded, might serve as the basis for a trial with survival as the primary endpoint. SER 1975. But Crager also told defendant and Pennington that he was worried that there was "no apparent way" that Actimmune could result in a survival benefit given that: (1) the lung function tests that were part of the primary endpoint indicated no apparent effect on lung function; and (2) no evidence from the trial explained how the drug might help IPF patients live longer. SER 1974, 1989-90.

On August 17, 2002, on his own initiative, Crager contacted Pharmanet, the contract research organization involved in collecting data for the trial, and asked it to analyze the survival time for subgroups of patients with FVCs greater and less than 60%. SER 1976-78. Companies can do post-hoc analyses, *i.e.*, analyses of data after the trial is done that are not pre-specified. SER 146-47. Post-hoc analyses may be done, for example, to better understand how to use the drug, once pre-specified analyses show evidence that it is working. *Id.* However, p-values for post-hoc subgroup analyses are "very hard to interpret," even when very low.[8] SER 2011.

After Crager received the subgroup results on August 21, and shared them with defendant and Pennington, defendant directed Crager to conduct additional analyses of mortality by breaking the patient population into subgroups of mild (FVC 71-100%), moderate (FVC 56-70%), and severe (FVC 0-55%) IPF

[8] While there are differing theories of statistical interpretation, SER 364-65, the testimony at trial showed that InterMune was using the basic rules set forth above in analyzing the results of the trial. SER 366, 1979.

patients.[9] SER 1980-82. Nowhere in the trial's SAP had these subgroups been identified or proposed as a basis for analyzing the mortality data. SER 1977.

Crager received the results from this second post-hoc subgroup analysis on August 22, 2002, and shared them with defendant. SER 1983-84. Defendant then told Crager to run the data again, this time for two subgroups, those with FVC greater than and less than 55%, thus combining the mild and moderate IPF sufferers into one group.[10] SER 1983-84. Harkonen's idea was to choose the parameters so as to "focus[] on that patient population that had the best outcome in terms of mortality." SER 2509. Defendant "indicated that they were going to have Michael Crager cut that data and slice it until they got the kind of results they were looking for." *Id.*

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[9] Defendant asked Crager to verify that those FVC parameters represented appropriate groupings for severe, moderate, and mild IPF. SER 1981-82. Crager conferred with pulmonologists, but was unable to confirm that defendant's proposed categories were well-established. Nevertheless, those were the parameters Crager ultimately asked the CRO to use. SER 1982-83. While mild, moderate, and severe IPF were generally accepted concepts, there were no precise generally accepted definitions to determine who fell into which category. SER 230, 612-13, 2508-09.

[10] At some point during this process, defendant called Rosenfield again to tell him that things were looking better because they had found a subgroup in which the drug actually seemed to work. SER 2864.

Crager ran those analyses, and again shared the results with defendant. On this try, only 6 of the 126 participants treated with Actimmune in the "mild to moderate group" died during the clinical trial, compared to 21 of the 128 patients in the corresponding placebo group, a result that represented a greater than 70% reduction in mortality, and yielded a p-value of 0.004.[11] SER 48.

At defendant's direction, some, but not all of the post-hoc subgroup analyses were faxed to the FDA on August 22, 2002.[12] SER 1988-92; ER 2034-44. The August 22 fax included only the subgroup analysis using the 60% cutoff. SER 1990-91. It did not include the other post-hoc FVC analyses. *Id.* Defendant told Crager not to send all of the post-hoc analyses "because we didn't want to make it look like we were doing repeated analyses [of the same endpoint] looking for a better result." SER 1991-92.

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[11] In other words, the p-value for the 60% FVC cut-off reflected something that would happen randomly only one in forty times. SER 588-89. By contrast, the p-value for the 55% FVC cut-off – the one used in the August press release – reflected a p-value that on its face appeared to show something that would happen randomly only one in 250 times. SER 589. Accordingly, based on p-values, the latter would appear more reliable. *Id.*

[12] A summary of the primary results were faxed to the FDA on August 21, 2002. SER 1988-90; ER 2015-33.

E. Harkonen Is Warned About Post-hoc Reanalysis of the Data

Defendant was told by more than one individual on more than one occasion that the trial had failed and that the post-hoc reanalysis was unreliable and inconclusive. SER 234-39, *see also* SER 446-47.

On August 16, 2002, Crager reported to defendant that the trial showed "no evidence of an effect on the primary efficacy endpoint, but that there was a trend in the survival data. And that we might want to follow up and do another trial." SER 1975.

On August 19, 2002, defendant and InterMune management met with the Data Monitoring Committee, including Dr. Fleming, to discuss the results. SER 447. Fleming told defendant that the results indicated that Actimmune had no effect on slowing the progression of IPF, and that none of the secondary endpoints achieved a statistically significant p-value. SER 447-49. As a result, "there was quite a strongly reinforced insight that . . . the trial had not provided a clinically meaningful effect." SER 448-49. After Fleming shared his views, which were shared by the other members of the DMC, SER 450, defendant instructed others to disinvite Fleming from participating in a subsequent call with the FDA, as well as a steering committee meeting. SER 1996-98, 2012.

On August 26, 2002, Dr. Stephen Porter, InterMune's Senior VP of Clinical Affairs and Chief Medical Officer, discussed with Harkonen and other InterMune scientific personnel the "fact that it was disappointing that the trial did not meet any of its endpoints" and that "[i]t was impossible to know whether these findings [the secondary endpoint of survival and the subgroup analysis] were real or not." SER 1131, 1133-36.

On August 27, 2002, Harkonen and a handful of other InterMune employees spoke unofficially with the medical review staff at the FDA about the results of the GIPF-001 trial and the additional analyses of the mortality data. SER 1134, 1136-37. The FDA medical review staff advised them that the GIPF-001 trial data were inconclusive, that the results were not adequate to get FDA approval for Actimmune to treat IPF, and that further clinical trials would be needed. SER 1137. As the minutes reflected, Dr. Walton stated that because "the physiologic measurements did not show any apparent treatment effect, the decrease in mortality in his opinion could be considered 'almost an anomalous finding in the face of no effect on pulmonary function and so warrants extra caution.'" SER 1725, 5618 (Ex. 671). Furthermore, the minutes reported, Dr. Walton said that

"'[t]here was no way to give [the survival data] a meaningful p-value in the face of the failed primary endpoint.'"[13] SER 5618 (Ex. 671).

F. Drafting the Press Release

Weeks earlier, while still waiting for the results of the GIPF-001 clinical trial, InterMune began planning a press release for those results. SER 2333. This press release was, according to the company's general counsel, the most important in the company's history. SER 3061-62, 3142. The "key target audience" for the press release was patients, doctors, caregivers, and patient family members. SER 2340; ER 1995. Defendant knew about and approved plans to disseminate the press release to doctors and patients as part of InterMune's sales strategy. SER 847-49, 851, 853-58, 2498-500, 2523, 2525, 2576, 5618 (Ex. 4).

Defendant worked with James Weiss, the head of Weisscomm, a communications firm, to draft the press release. SER 2325-56. Weiss was not a doctor or a statistician. SER 2325-26. Weiss's main information about the results came from defendant, who informed Weiss that the trial results were generally

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[13] After that meeting, defendant told Dr. Marianne Armstrong, InterMune's Senior Vice President of Global Regulatory Affairs and Corporate Compliance, who had drafted the minutes, that he was "very disappointed" that she had taken minutes. SER 1625. Armstrong testified that it was standard operating procedure to take minutes of their calls with the FDA, and that she had previously shared meeting minutes from other calls with the FDA with defendant without complaint. SER 1625.

positive in terms of showing some survival benefit, although the primary endpoint had not been met. SER 2335-36, 2350. In the past, Weiss had had access both to the raw data and to InterMune's medical staff when working on pharmaceutical-related press releases. SER 1152, 2349-50. This time, although Weiss asked defendant for access to both, he got neither. SER 2349-51, 2353-54.

Defendant and Weiss began trading drafts on August 25, 2002, and worked on the press release until it was completed on August 27, 2002. SER 5618 (Ex. 13-14). On August 25, Steven Porter, the Vice President of clinical research in charge of pulmonary research, complained to defendant about the short amount of time between the clinical people learning the trial results and the planned press release. SER 1125-26. Porter specifically told defendant in an email that it was a mistake to publish a press release without adequate time for the clinical scientists to think about it. SER 1126. "I can tell . . . that the data is not totally straightforward," he wrote, and asked for 24 hours. *Id.*

However, before August 27, 2002, no one other than Harkonen and Weiss had seen drafts of the press release. SER 2348-49. On that day, during an off-site meeting, Armstrong, Porter, and Crager briefly viewed some parts of the release by looking over Weiss's shoulder while he edited the draft on a laptop computer. SER 2357-60. At that meeting, Crager talked briefly to Weiss about fixing an

incorrect p-value, but after that, defendant told Crager not to bother Weiss because Weiss was busy. SER 2003-04. At that same meeting, when Armstrong asked defendant if he wanted her or InterMune's regulatory division involved with the writing of the press release, defendant told her not at that time, that he was working on a draft, and that he would share it with her later. SER 1611-12.

When Armstrong, Porter, and Crager gathered around Weiss to try to read the press release, defendant ordered Weiss out of the room and sent him back to InterMune's headquarters. SER 2360-61. Cory testified that a visibly upset defendant castigated Weiss for sharing the draft press release with others. SER 2517-18.

Crager told people that he was available to help, and stayed at the office until 7 p.m. the night before the press release was issued. SER 2005, 2008. When he asked Weiss about helping, Weiss told him he did not know whether he was allowed to share the draft with Crager, and that he would check with defendant. SER 2085-86. At trial, Weiss testified that he thought there was sufficient time that night for clinical employees to review the draft. SER 2428.

Some Intermune employees, including Keith Katkin, the Vice President of Pulmonary Marketing, provided input on the key messages they thought the press release should include, and Katkin, the Vice President of Pulmonary Marketing,

received a copy of the release late on the 27th, so that he could prepare for the roll out of the press release to the field sales force the next morning. SER 866-67, 2346, 5618 (Ex. 49, 51).

Although the firm's general counsel reviewed drafts of the release before it was issued, defendant did not tell him that the FDA had indicated skepticism about the results, or that InterMune's clinical division had asked for more time to review the data before the release went out, or that ultimately, the clinical division did not get to review the press release before it went out. SER 2898-99, 3042-45. Rosenfield was relying on the clinical and regulatory divisions to make sure that the scientific aspects of the release were correct, and he testified that defendant misled him into believing that InterMune's clinical and regulatory staff had reviewed the press release; Rosenfield testified that he would not have signed off on the press release had he known otherwise. SER 3045, 3056, 3050-52. In fact, aside from defendant, no one with a clinical or statistical background or who had reviewed the clinical trial data (including Crager, Porter, and Armstrong) was able to review the press release in its entirety before it was issued. SER 2350.

G. Issuance of the Press Release and Its Aftermath

On August 28, 2002, Harkonen issued the press release, the headline of which stated: "InterMune Announces Phase III Data Demonstrating Survival

Benefit of Actimmune in IPF." ER 1906-09. The subheading read: "Reduces Mortality by 70% in Patients with Mild To Moderate Disease." ER 1906. The release stated that data from the GIPF-001 trial demonstrated a statistically significant survival benefit in patients with mild to moderate IPF with a p-value of 0.004, without stating that this was not a primary, secondary, or even a pre-specified exploratory endpoint for the trial. ER 1906. The release also stated that the data "confirm[ed] the survival benefit seen" in the Ziesche trial. ER 1906.

The press release also stated that "[t]here was also approximately a 10% relative reduction in the rate of progression-free survival associated with Actimmune versus placebo, the trial's primary endpoint, but this was not a statistically significant difference." *Id.* The section describing the clinical trial details included a similar statement, but then immediately noted that "[i]mportantly, Actimmune also demonstrated a strong positive trend in increased survival in the overall patient population, and a statistically significant survival benefit in patients with mild to moderate IPF." ER 1907.

The press release did not state that the clinical trial had also missed all of its secondary endpoints, although on the second page, it did give a p-value for the survival endpoint. ER 1906-09. Nor did the press release state that the mild-to-moderate IPF patient analyses were post hoc and not part of the SAP. *Id.* The

press release quoted defendant as stating that "these results will support use of Actimmune and lead to peak sales in the range of $400-$500 million per year, enabling us to achieve profitability in 2004 as planned."[14] *Id.*

The press release was posted on InterMune's website, and sent to a wire service for nationwide release to news outlets. SER 191-92. Specifically, it was sent to roughly 4,000 newsrooms nationwide, and 3,500 online databases and websites. SER 191-92. At the time it was issued, the press release was the only source of information available to the public about the trial results. SER 451-52.

On September 5, 2002, defendant attended the Biocentury Newsmakers Conference in New York, where he addressed financial analysts, and told them that the InterMune sales representatives had access to the press release and were using it. SER 2531. The evidence showed that sales representatives thought the press release very effective, and used it with doctors to convince them to prescribe Actimmune for IPF patients. SER 2292, 2524-26, 5618 (Exs. 64, 82, 89, 96, 331).

After the press release came out, defendant was repeatedly told that the press release was fraudulent. When Dr. Fleming first read the press release after it

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[14] The release also included a quote from Dr. Raghu. ER 1906-09. Raghu testified that defendant called him days before the press release and told him the trial was a success, and based on defendant's positive description of the data, Raghu made statements similar to those in his quote in the press release. SER 635-39. Raghu did not see the press release before it was issued. SER 638.

came out, he was "stunned," and found it to be "a serious misrepresentation of [the] truth as I understood it." SER 453. He wrote a letter harshly criticizing the press release and sent it to InterMune. *Id.*; SER 5618 (Ex. 3). In his letter, Fleming noted that the trial failed to achieve statistical significance on the primary endpoint. SER 455. Fleming also noted that even discounting the failure to hit the primary endpoint, and taking the p-values for the secondary endpoints as a basis for determining reliability, none of the secondary endpoints achieved statistical significance either. SER 457. Moreover, as Fleming testified at trial, it was particularly problematic to suggest that a trend towards survival was real because the results of the GIPF-001 trial indicated that Actimmune had no effect on lung function. SER 461-62. Fleming also noted that using the press release's FVC cutoff meant that in patients with severe IPF, there was a *higher* deathrate among those on Actimmune than among those on the placebo, not what one would expect to see if Actimmune truly helped IPF patients live longer. SER 465-66.

After he received Fleming's letter, defendant flew to Seattle to meet with him to talk about corrective action. SER 474-75. During a subsequent meeting, however, defendant falsely asserted to Fleming that the biostatistics and the clinical divisions had been involved in the August 28th press release. SER 474-75, 483-84.

Defendant also met with Dr. Raghu at the European Respiratory Society meeting in Stockholm that September. SER 646. Dr. Raghu testified that defendant was very apologetic about the press release, and that defendant told him that he was drafting a second press release to set the record straight. SER 646.

In addition to Dr. Fleming and Dr. Raghu, defendant was told by Armstrong that Dr. Walton was "truly dismayed" with the press release and thought that it "misled" the public, and that Dr. William Schwieterman, a former Division Director at the FDA and an InterMune consultant working on clinical trial design, was also upset by the press release, calling it "the perfect example of how not to write a press release." SER 1629-42, 5618 (Exs. 136, 140). Defendant responded by telling Armstrong he did not want Schwieterman's opinion raised at an upcoming committee meeting. SER 1642.

Although InterMune issued a subsequent press release on September 18, 2002, defendant never retracted the original one; the sales force continued to use the August 2002 press release, not knowing that there was a problem with it. SER 890, 980, 1062, 1463, 2260, 2579-80.

SUMMARY OF ARGUMENT

I. The evidence at trial showed beyond a reasonable doubt that defendant knowingly engaged in a scheme to defraud by issuing a false or fraudulent press release. Although the clinical trial indisputably failed by all of its own measures and was even a failure by Intermune's own internal criteria, defendant's press release presented the trial as a success: "InterMune announces Phase III data demonstrating survival benefit of Actimmune in IPF;" "reduces mortality by 70% in patients with mild to moderate disease." Moreover, the body of the press release omitted critical information that cast doubt on the reliability of those claims.

A reasonable factfinder could also have found that defendant had the requisite knowledge and intent to defraud. Defendant was told repeatedly before the press release was issued that the clinical trial had missed all of its own pre-determined endpoints, and that no firm conclusions about a survival benefit could be drawn from the data. Moreover, in a departure from his company's normal practice, defendant affirmatively prevented his technical staff, who had the background and expertise to evaluate the veracity of the press release, from reviewing it. Finally, defendant specifically linked the results to projected

earnings for his company in the press release itself. A positive announcement would bolster sales, while a negative one would result in them flatlining.

A reasonable factfinder could also have found that the statements were material. At the time the press release was released to over 4,000 newsrooms and 3,500 websites, it was the only publicly available material summarizing the clinical trial results. Indeed, the evidence showed that it was intended to be – and in fact was – used as part of the company's marketing strategy.

II. There is no First Amendment shield for making knowingly false statements with an intent to defraud even if they concern scientific matters. Nor should there be. As the district court correctly found and the evidence plainly shows, "Harkonen is seeking to protect more than just good-faith scientific debate." The speech here was a press release, intended to be used in sales and marketing, not a peer-reviewed publication. It referred to Actimmune, a specific commercial product on the market, and was unquestionably disseminated for commercial benefit. All of these facts take this case out of the realm of pure scientific debate.

III. Defendant had fair notice that misrepresenting the results of the clinical trial was false and fraudulent within the meaning of the fraud statute. Defendant's argument to the contrary misconstrues the nature of his crime and the

controlling case law. A person of ordinary intelligence would understand that the law prohibits making knowing misrepresentations about clinical trial results with an intent to defraud in order to increase drug sales.

IV. The district court did not err by not instructing the jury on a good faith defense. Consistent with this Court's caselaw, the district court adequately instructed the jury on intent to defraud, and no more is legally required.

V. The district court did not abuse its discretion in denying the defendant's motion for a new trial based on the government's post-trial production of some Veteran's Administration documents regarding the VA's possible use of Actimmune. The documents produced had little, if any, exculpatory value, and taken cumulatively, failed to cast any serious doubt as to the materiality of defendant's false and fraudulent statements. In light of their negligible weight, the failure to produce these documents before trial was hardly prejudicial.

The district court also did not abuse its discretion by refusing to grant a new trial based on a government brief filed in the Supreme Court contending that adverse event reports on a drug could be material to reasonable investors and so trigger disclosure requirements under federal securities laws. In so doing, the district court correctly concluded that the government's position in that case was argument, not evidence, defendant amply pursued arguments about statistical

debates during cross-examination, and nothing in the ensuing Supreme Court decision undermined the substantial evidence that defendant knew that the GIPF-001 trial results did not establish the causal relationship announced in the press release.

VI. The district court erred in calculating the defendant's advisory sentencing range under U.S.S.G. § 2B1.1 by refusing to attribute any loss amount to defendant. The court rejected the government's actual loss arguments, but failed to consider the evidence of intended loss, including evidence that Harkonen had touted the drug's potential to create hundreds of millions of dollars in sales as an effective treatment for the lung disease. This was error.

Moreover, the district court legally erred by refusing to apply the vulnerable victim enhancement under U.S.S.G. § 3A1.1(b)(1) even though Harkonen knew that the press release would be provided to patients suffering from a serious disease for which there is currently no treatment. Instead, the district court improperly imported the definition of victim specific to U.S.S.G. § 2B1.1, which concerns individuals who sustained economic losses. Accordingly, this Court should reverse defendant's sentence and remand for resentencing.

ARGUMENT

I. A RATIONAL TRIER OF FACT COULD HAVE FOUND BEYOND A REASONABLE DOUBT THAT DEFENDANT WAS GUILTY OF WIRE FRAUD

A. Standard of review

This Court reviews de novo challenges to the sufficiency of the evidence. *See United States v. Stewart*, 420 F.3d 1007, 1014 (9th Cir. 2005). The appellate court does not "ask itself whether *it* believes that the evidence at trial established guilt beyond a reasonable doubt," but rather whether, viewing "*all of the evidence*" in the light most favorable to the government, "*any* rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt." *Jackson v. Virginia*, 443 U.S. 307, 318-19 (1979) (emphasis in original) (internal quotation marks omitted); *see also United States v. McKenna*, 327 F.3d 830, 838 (9th Cir. 2003). This standard "gives full play to the responsibility of the trier of fact to resolve conflicts in the testimony, to weigh the evidence, and to draw reasonable inferences from basic facts to ultimate facts." *Jackson*, 443 U.S. at 319.

In addressing the sufficiency of the evidence, this Court should not reverse even when an innocent construction is not any less likely than the incriminating explanation advanced by the government. *United States v. Nevils*, 598 F.3d 1158, 1167 (9th Cir. 2010) (en banc). "Circumstantial evidence and inferences drawn

from it may be sufficient to sustain a conviction."[15] *United States v. Shea*, 493 F.3d 1110, 1114 (9th Cir. 2007) (internal quotation marks omitted).

B. This Court Should Reject Defendant's Sufficiency Challenges

To prove a violation of the wire fraud statute, the government must show a scheme to defraud, use of wires in furtherance of the scheme, and the specific intent to defraud. *United States v. McNeil*, 320 F.3d 1034, 1040 (9th Cir. 2003).

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[15] Defendant and amici argue that this Court should discard its settled approach to sufficiency challenges in favor of extending the independent review applied to a determination of actual malice in *Bose Corp. v. Consumers Union*, 466 U.S. 485, 510-11 (1984), to the wire fraud context. *Cf. Illinois, ex rel. Madigan v. Telemarketing Associates, Inc.*, 538 U.S. 600, 620-21 (2003) (court may but is not required to impose independent review in a state fraud case). *Prete v. Bradbury*, 438 F.3d 949, 960 (9th Cir. 2006), and *United States v. Hanna*, 293 F.3d 1080, 1088 (9th Cir. 2002), expressly draw a distinction between "historical questions of fact," involving credibility determinations, the weighing of conflicting evidence, and the elements of statutory liability, which are reviewed for clear error, and constitutional questions of fact (such as the existence of actual malice), which are not. *See also SEC v. Pirate Investors*, 580 F.3d 233, 242-43 (4th Cir. 2009) (declining to apply *Bose*'s standard of review to scienter); *Novartis v. FTC*, 223 F.3d 783, 787 n.4 (D.C. Cir. 2000) (applying clear error standard to determination of materiality in deceptive advertising case, rather than independent review). And as *Hanna* makes clear, independent review does not amount to a de novo reweighing of all the facts. 293 F.3d at 1088. First, deferring to the jury's findings on historical facts, credibility determinations, and elements of statutory liability, this Court must consider whether the verdict is supported by substantial evidence; if the appellate court finds that it is, it then conducts an independent review of the record to determine whether the facts as found by the jury establish the core constitutional fact. *Id.*

By its terms, the statute does not exempt conduct that otherwise satisfies its requirements based on the subject matter of the statement.

1. The evidence showed a scheme to defraud

a. The evidence showed the press release was false and misleading

The evidence showed that defendant's statements in the press release were false and misleading representations about the results of the trial, not simply less popular opinions in a scientific debate. In concluding that the press release furthered defendant's scheme to defraud, a rational juror could have relied on the fact that the release presented the trial results as a success, when by defendant's own criteria, the trial was a failure.

As the district court found, there was "sufficient evidence for the jury to conclude beyond a reasonable doubt that multiple statements contained in the press release were false or fraudulent." ER 49. First, the jury could have found that the press release's headline claiming that the Phase III data "demonstrat[ed a] survival benefit" was objectively untrue, in light of testimony that the secondary endpoint of survival failed to achieve statistical significance. Second, the jury could have found that the press release asserted a causal relationship between Actimune and the survival of IPF patients, when the data did not establish any such relationship. More specifically, the jury could have concluded that a sub-

0.05 p-value did not demonstrate a causal relationship. In fact, the press release misleadingly equated a p-value of less than 0.05 with statistical significance, causation, and efficacy without any adjustment for context, including secondary endpoints and post-hoc analyses.[16] ER 50.

The p-value as portrayed in the press release was rendered false by the complete omission of any mention that the only results with a p-value less than 0.05 – the subgroup analysis of patients with mild to moderate IPF – were observed only after InterMune engaged in multiple retrospective analyses. *See* ER 50. Moreover, the press release also omitted the fact that the clinical trial protocol had nine secondary endpoints – of which survival was ranked only seventh most relevant–and that all nine failed to produce statistically significant results. As the court recognized, these omissions of "critical information," especially given that at the time of the press release there was no publicly available data for the GIPF-001 trial to enable interested individuals to verify the results, were more than sufficient to establish falsity. *Id.*

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[16] Defendant argues that the district court erroneously attributed talismanic significance to the p-values in this case. AOB 3. In fact, as the district court pointed out, defendant did so in the press release by relying on the 0.004 p-value without acknowledging the factors that made that p-value a less than reliable indicator of the clinical trial's success. ER 50.

Finally, the jury could have concluded that the press release as a whole was false or fraudulent because the clinical trial failed to meet its primary endpoint as well as all nine secondary endpoints, but the press release nonetheless described the study as a success. *See* ER 50.

b. The wire fraud statute encompasses this speech

Defendant argues that this Court should find that the wire fraud statute does not extend to statements about scientific speech in general and the medical import of clinical trial results in particular. AOB 36-41. This Court should decline to carve out such an exemption.

Defendant argues that *Am. Sch. of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 100-01, 104-05 (1902), holds that federal fraud statutes cannot apply to "mere matters of opinion upon subjects which are not capable of proof as to their falsity." But *McAnnulty* simply held that a statute allowing the postmaster to refuse to deliver fraudulent materials did not apply to materials concerning mind-healing because there was no way to evaluate the truth or falsity of that claim as a factual matter. 187 U.S. at 100-01, 104-05.

Moreover, the second case on which defendant relies, *Reilly v. Pinkus*, 338 U.S. 269, 274 (1949), expressly repudiates the reading of *McAnnulty* that defendant advocates. *See Reilly*, 338 U.S. 269 (rejecting the proposition that the

testimony of "even the most experienced of medical experts can never rise above mere opinion" and holding that "[t]he *McAnnulty* holding does not go so far"); *see also Leach v. Carlile*, 258 U.S. 138, 139-40 (1922) (distinguishing *McAnnulty*).

In *Reilly*, the Supreme Court held that, as a statutory matter, advertisements could not be excluded from the mails on grounds of fraud "when the charges concern medical practices in fields where knowledge has not yet been crystallized in the crucible of experience. For in the science of medicine, as in other sciences, experimentation is the spur of progress." 338 U.S. at 274. Nevertheless, the *Reilly* Court upheld the fraud determination at issue there, notwithstanding "slight" scientific uncertainty over whether the product at issue, kelp (or, more specifically, the iodine within kelp), was, as the defendant had claimed, an effective weight reducer. *Id.* The Court explained that "[d]espite subtle qualifying phrases, it is difficult to read these advertisements as a whole without receiving the impression that * * * kelp is a sure and drastic weight reducer; that a user can reduce without uncomfortably restricting his usual ample diet of fattening foods; that the treatment is absolutely safe and harmless to people of all ages, to the ill and the well." *Id.* at 274-75. Accordingly, the Court held, even assuming that "medical opinion is yet in a state of flux" on the question of kelp's efficacy, "there was sufficient evidence to support the findings that the efficacy of the plan as a

whole was misrepresented in respondent's advertising." *Id.* at 274. Moreover, the Court held, those representations "went beyond permissible puffing of a seller's wares; they were material representations on which credulous persons . . . were entitled to rely." *Id.* Those representations, "if made with an intent to deceive, fall squarely within the type that in *Leach v. Carlile*, were held to justify findings of fraud." *Id.*

Here, the government did not prosecute defendant because he was wrong about the efficacy of Actimmune. Instead, defendant was convicted based on a press release that was intended to be used to generate drug sales and that contained representations that the clinical trial data affirmatively demonstrated efficacy – something that they manifestly did not do. Experimentation is indeed "the spur of progress," but a knowing misrepresentation about the significance of experimental results made for purposes of generating drug sales is not. Nothing in *Reilly* suggests otherwise.

Moreover, the entire regulatory scheme by which the FDA evaluates claims regarding the efficacy of drugs is predicated on the assumption that those claims are matters of fact, capable of empirical determination. *Cf. United States v. Campbell*, 897 F.2d 1317, 1321 (5th Cir. 1990) (rejecting argument that statement about availability of tax benefits was only an opinion and thus could not be false

or fraudulent). As this Court held in *Fanning v. Williams*, 173 F.2d 95, 96-97 (9th Cir. 1949), "[i]f we reject expert medical findings, based as they are upon years of research, observation and experience, on the ground that they are not substantial and are mere opinion, we close the door to the prevention of a variety of frauds and impositions that may be imposed upon the public and disregard accepted and established practice relative to competent and relevant testimony."

c. The government proved this fraud with competent evidence

Defendant and amici argue that this Court should graft an additional requirement onto the wire fraud statute and reverse absent evidence of a medical consensus "admitting of no reasonable doubt, that the charged statements were thoroughly discredited and objectively false." AOB 42. No case supports such a drastic change in the standard governing sufficiency challenges. The government was only required to prove beyond a reasonable doubt that defendant engaged in a scheme or plan to defraud by making false or fraudulent statements, that the statements were false or fraudulent, that defendant made them knowingly, and that he made them with the intent to defraud. As the district court found, the government met this burden "convincingly." ER 57.

Defendant also asks this Court to impose a categorical requirement on the type of evidence the government needed to meet its burden of showing fraud.

Specifically, he argues that proof of the press release's falsity must come from an expert, and then in a footnote criticizes the government for improperly treating its witnesses as expert witnesses.[17] AOB 39-40; *id.* at 39 n.12. Nevertheless, defendant argues, because the government's witnesses conceded that their opinions admitted room for disagreement, defendant cannot be convicted where there is conflicting medical expert testimony. AOB 40-41.

As an initial matter, this case was not a battle between differing medical witnesses. Defendant chose not to put on a single witness qualified to discuss medical or statistical issues, even though he had noticed six medical or statistical experts. And, the testimony among the government's witnesses who were qualified to discuss those issues was consistent about the fact that these post-hoc

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[17] The district court properly found that the testimony of Drs. Crager and Fleming regarding how to interpret statistical results was properly before the jury. ER 51-52, 66. Indeed, defendant did not seek to exclude opinion testimony by Dr. Fleming, despite being aware that the government having listed both him and Dr. Crager as potential experts. ER 51-52. Moreover, at no time did defendant object to any of Crager's or Fleming's testimony about general principles of biostatistics, or more specifically to their testimony about the inherent problems of interpreting secondary endpoints and post-hoc subgroup analyses. ER 52. Because the witnesses were properly noticed and because defendant did not object before the district court, he has no claim of prejudice. *United States v. Figueroa-Lopez*, 125 F.3d 1241 (9th Cir. 1997). Even if the testimony was improperly admitted, it must be considered when the Court evaluates the sufficiency of the evidence. *See Lockhart v. Nelson*, 448 U.S. 33, 41-42 (1988) (in reviewing sufficiency, all evidence, even if wrongly admitted, is considered).

subgroup analyses, while potentially useful indicators for future research, were not reliable.

Defendant's attempt to cite examples to the contrary is unavailing. Thus, for example, defendant seeks to make much of the fact that Porter approved the submission of the Final Clinical Trial Report to the FDA, which stated that a stronger survival benefit was demonstrated, and that he testified at trial that it was accurate to say the subgroup analysis "showed a survival benefit." AOB 41. But in each of those instances, the context made it clear that the analysis was both post-hoc and exploratory. Indeed, the Final Clinical Trial Report frankly acknowledged that there had been a number of different attempts to analyze the data using the same metric but different parameters – exactly the sort of information the omission of which from defendant's press release was so misleading. ER 2302.

d. The district court properly evaluated the evidence

Defendant claims that in affirming the verdict, the district court ascribed a talismanic importance to a particular p-value. *See, e.g.,* AOB 3. It did not. To the contrary, it found that one of the ways in which the press release was false and misleading was that it presented a p-value that by itself suggested statistical reliability, and omitted the information that undercut that reliability. ER 50.

Based on the evidence at trial, a reasonable juror could well have found that the conclusive statements in the press release about a demonstrable, quantifiable, statistically reliable survival effect in a particular subgroup was irreconcilable with the testimony that that trend was both unreliable and inconclusive. Here, both Crager and Fleming testified that the GIPF-001 trial utterly failed to meet every single one of its endpoints. SER 447-49, 1972-73.

As Fleming explained, if a clinical trial missed its primary endpoint, "one has to be incredibly cautious about that [achieving a statistically significant result on a secondary endpoint] . . . . [Y]ou clearly cannot interpret the p-values on those secondary measures the way you would interpret the p-value on the primary endpoint." SER 441-42.

In this case, the data presented in the press release was not even of a pre-specified secondary endpoint but an after-the-fact subgroup analysis – in fact, one of multiple after-the-fact analyses done by Intermune. Although it included some relevant information, defendant's press release failed to include other pertinent information, such as the fact that this was one of a number of post-hoc analyses.

2. The evidence showed that defendant had the requisite knowledge and intent to defraud

Defendant argues that the evidence did not suffice to show knowledge of falsity and intent to defraud. Specifically, defendant contends that "knowledge that some others disagreed with his view does not prove beyond a reasonable doubt that [defendant] knew that his own view was false." AOB 59. But "[i]t is settled law that intent to defraud may be established by circumstantial evidence." *United States v. Rogers*, 321 F.3d 1226, 1230 (9th Cir. 2003). Furthermore, intent may be inferred from misrepresentations made by a defendant, *see United States v. Lothian*, 976 F.2d 1257, 1267-68 (9th Cir. 1992), and the scheme itself may be probative circumstantial evidence of an intent to defraud. *United States v. Plache*, 913 F.2d 1375, 1381 (9th Cir. 1990). "Both direct and circumstantial evidence can be used to establish knowledge and [both] are given the same weight." *United States v. Sayakhom*, 186 F.3d 928, 943 n.8 (9th Cir. 1999); *see also United States v. Ciccone*, 219 F.3d 1078, 1084 (9th Cir. 2000) ("The government can establish knowledge of a fraudulent purpose by circumstantial evidence.").[18]

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[18] Amici PhRMA claims that because the government did not introduce evidence at trial of defendant's own understanding of biostatistics, this alone should have required defendant's acquittal. But the government may prove its case based on any relevant, probative evidence, whether direct or circumstantial. Moreover, the government did introduce evidence about what defendant had been told repeatedly about the results of the GIPF-001 clinical trial, the limitations of

First, based on criteria defendant himself developed, the trial was a failure. Before defendant or the company received the results, they tried to anticipate how to react to those results, depending on whether the trial was a success, was equivocal, or was a failure. SER 2488-96. Failure was defined as the clinical trial missing both its primary and all its secondary endpoints – as in fact it did. SER 2496. Nevertheless, the press release posited the results as a success.

Second, defendant's actions suggest his own knowledge of the limitations of the subgroup analyses. Defendant specifically directed that only one set of post-hoc subgroup analyses be sent to the FDA. SER 1988-92, 5618 (Exs. 44, 46). Defendant did not want to send additional subgroup analyses to FDA, lest it look as if InterMune was looking for a better result. SER 1990-92. That too suggested that defendant understood how the results should be evaluated – and omitted that information from the press release.

Third, the evidence shows that defendant had been repeatedly told that the results of the subgroup analysis were unreliable and inconclusive. The testimony at trial established that prior to the issuance of the release, Dr. Walton, Dr. Crager, Dr. Porter, and Dr. Fleming all discussed the clinical trial's failure to meet its pre-specified endpoints, the unreliability of the post-hoc subgroup analyses, and the

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the data, and their inconclusiveness. *See supra* Part I.

reasons why no firm conclusions could be drawn from that data. SER 368-70, 447-49, 1131-32, 1137-40, 1289-91, 1975-76; *see also* ER 54 (district court recounts testimony establishing that defendant knew results were unreliable).

Moreover, defendant's motivation for fudging the trial results was likewise clear given his statement in the press release about Actimmune's future sales, and his presentations forecasting sales of Actimmune for IPF increasing after the trial results were issued. SER 2488-2496, 5618 (Exs. 1, 215 (InterMune 2002 10-K), 33 (July 2001 National Sales Meeting), 115 (September 2002 BioCentury Newsmakers Conference presentation); 31 (June 2002 Presentation slides to Board)). In addition, defendant knew and approved the plan that the press release be disseminated to doctors and patients in order to influence sales. SER 847-49, 851, 853-58, 2498-500, 2523, 2525, 2576. As InterMune's general counsel stated, this was the most important press release in the company's entire history. SER 3046, 3061-62, 3142; *see also* ER 55 (district court recounts evidence of defendant's intent to defraud).

As the district court correctly found, that financial motivation coupled with "the efforts engaged in by Harkonen to prevent certain individuals, both outside and inside InterMune, from reviewing the press release serves as powerful circumstantial evidence of his intent to defraud, as well as his knowledge of

falsity." ER 55. And the evidence showed that it was. Defendant made sure that Armstrong and Crager never saw a complete draft, and when they tried to look at the draft while Weiss was working on it, defendant removed Weiss from the meeting and sent him back to the company's offices. SER 2004, 2008, 2085-86, 2357-61, 2517-18. Moreover, the company's general counsel, on whom defendant relied to establish his own good faith, testified that (1) he felt that defendant had led him to believe that clinical and regulatory people had reviewed the draft, when in fact they had not; (2) he was relying on people from InterMune's clinical and regulatory departments to review the press release before it went out; and (3) he would never have approved it if he had known that they had not had a chance to review it. SER 3041, 3045-46, 3050-52, 3056.

Defendant suggests that the evidence shows that there simply was not time to include others in the drafting process. AOB 63. That, however, is simply not true. Defendant called Weiss with the results of the trial the weekend before August 28, 2002. SER 2334-36, 2350. Weiss prepared further drafts of the press release that he emailed only to defendant, spoke to defendant frequently about revisions to the press release, and requested – but never saw – the trial results. SER 2337-600, 5618 (Exs. 13, 14, 55). Moreover, other individuals like Rosenfield, the general counsel, reviewed several drafts, and sales and marketing

were able to weigh in with what they viewed as key messages. SER 866-67, 2346, 2898-99, 3042-45. In short, a rational juror could conlcude that from the time he learned of the failed results until he authorized the issuance of the press release, defendant had the motive and the intent to mislead his target audience into believing that the GIPF-001 trial showed that Actimmune was an effective treatment for IPF.

3. The evidence showed that the charged statements were material

A statement is material for wire fraud purposes if it has the natural tendency to influence or be capable of influencing the person to whom it was addressed. *United States v. Jenkins*, 633 F.3d 788, 802 n.3 (9th Cir. 2011). There is no requirement that the statement actually influence the person. *Id.*

As noted above, that press release was the only public information available about the clinical trial results at that time. It was provided to sales representatives as a tool for marketing Actimmune. SER 2292, 2524-26, 5618 (Exs. 64, 82, 89, 96, 331). Indeed, there was testimony about how useful the sales force found the press release in drumming up sales for IPF. *Id.* And, although actual reliance is not required, Actimmune sales did go up after the press release was issued. That is more than sufficient to demonstrate materiality.

Nevertheless, defendant contends that the jurors could not determine materiality in the absence of expert testimony because they lacked the experience and training to decide what would be material to a pulmonologist treating IPF. That argument fails for three reasons.

First, the case that defendant cites imposes no such requirement; indeed, it does not even address materiality or expert testimony, let alone both. *See Transue v. Aesthetech Corp.*, 341 F.3d 911, 916-17 (9th Cir. 2003) (addressing whether a strict liability jury instruction was required for a claim of design defect relating to breast implants).

Second, the jury was capable of making a determination on this point without expert testimony. A reasonable jury could conclude that doctors would take into account a press release, which was at the time the only publicly available information on the clinical trial.

Third, defendant assumes, contrary to the record in this case, that the only audience for the press release was doctors. In fact, the evidence at trial showed that the press release was also intended to target patients with IPF, an incurable and fatal disease with no known cure or effective treatment. The press release misleadingly reported that the GIPF-001 trial to test Actimmune's efficacy had demonstrated a survival benefit which it attributed to Actimmune. A patient with

IPF reading that release might well ask their doctor about Actimmune.[19] This evidence was more than sufficient to demonstrate that the press release was capable of influencing its target audience.

II. THE FIRST AMENDMENT DOES NOT BAR DEFENDANT'S WIRE FRAUD CONVICTION

A. Background

Before trial, defendant moved to exclude protected First Amendment speech, or, in the alternative, to dismiss the indictment. CR 88; ER 2891. The district court denied defendant's motion in an 18-page written order, holding that "[p]lainly, Harkonen is seeking to protect more than just good-faith scientific debate." ER 159; *see* ER 144-61. The district court recognized that "speech is protected by the First Amendment if it is a *bona fide* scientific and educational speech that appears in independent and peer-reviewed sources, such as a journal article reprint or a medical textbook." ER 151. The district court also acknowledged that "questions remain about when such 'pure' speech gets converted to a 'less pure' form of commercial speech when a drug company is

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[19] *United States v. Goyal*, 629 F.2d 912, 915 (9th Cir. 2010), is not to the contrary. As the district court here noted, in *Goyal,* the jury had no basis for concluding that an improper accounting method was material to investors as there was no evidence regarding the effects of the accounting method on company revenues. Here, the very nature of the press release was designed to get the word out that Actimmune was beneficial for treating IPF.

involved, *e.g.*, by funding the studies or by disseminating the speech through various promotional activities. . . ." *Id.* Those questions, the court concluded, "are of no moment here because nowhere does the indictment invoke any 'pure' scientific speech." ER 151-52.

More specifically, the district court held that Harkonen's status as a doctor, the fact that the press release presented data and statistical analyses, and the fact that the dissemination of the release may have generated vigorous debate in the pulmonological and pharmaceutical analyst community did not make the press release pure scientific speech. To the contrary,

> that the speech is a press release and not a peer-reviewed publication, that it refers to a specific commercial product on the market (Actimmune), and that it was unquestionably disseminated for commercial benefit (*e.g.*, the first line notes InterMune's Nasdaq stock symbol), are allegations that take the speech at issue outside the realm of pure scientific speech and move it towards the realm of commercial speech.

ER 152 (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-68 (1983) (noting that whether form of speech is an advertisement, whether it refers to a specific product, and whether there is a clear economic motivation behind the speaker's activities provide strong support that speech is commercial)).

The district court also rejected defendant's argument that the speech at issue could never be fraudulent because it was, under *Reilly*, "no more than 'opinion' in a field where imperfect knowledge made proof 'as of an ordinary fact impossible.'" 338 U.S. at 273-74. As the district court held, *Reilly* explicitly rejected the argument that a finding of fraud is barred "'whenever there is the least conflict of opinion as to curative effects of a remedy.'" ER 153 (quoting *Reilly*, 338 U.S. at 273-74). Accordingly, the district court held, defendant's argument that the First Amendment barred a finding of fraud was belied by the allegations of the indictment. ER 153.

Defendant renewed his First Amendment challenge after trial. CR 247. The district court rejected it, finding that "[t]he jury concluded that Harkonen committed wire fraud by knowingly issuing false or fraudulent statements in the August 28, 2002 press release with an intent to defraud." ER 59. As a result, the district court concluded, "the First Amendment provides Harkonen with no defense from his conviction, as 'it is well settled that the First Amendment does not protect fraud.'" ER 59 (quoting *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1123 (D.C. Cir. 2009), and citing *United States v. Lyons*, 472 F.3d 1055, 1066 (9th Cir. 2007)).

B. Standard of Review

The denial of a motion to dismiss based on a violation of constitutional rights is reviewed de novo. *See United States v. Reveles-Espinoza*, 522 F.3d 1044, 1047 (9th Cir. 2008) (due process).

C. The First Amendment Is Not Implicated Here

1. The First Amendment does not protect knowingly false statements made with the intent to defraud

Defendant has been found guilty beyond a reasonable doubt of making statements that he knew to be false and misleading and to have done so for the purpose of defrauding his audience. This is a classic case of fraud, which is not even arguably protected by the First Amendment, which, the Supreme Court has repeatedly and unequivocally held, "does not shield fraud." *Illinois ex rel. Madigan v. Telemarketing Assocs., Inc.*, 538 U.S. 600, 612, 620 (2003) (elements such as scienter and materiality provide the requisite breathing room for speech that is in fact protected); *see San Antonio Cmty. Hosp. v. So. California Dist. Council of Carpenters*, 125 F.3d 1230, 1239 (9th Cir. 1997) ("The First Amendment does not protect fraud."); *see also BE & K Constr. Co. v. NLRB*, 536 U.S. 516, 531 (2002) (false statements unprotected for their own sake); *Hustler Magazine, Inc. v. Falwell*, 485 U.S. 46, 52 (1988) ("[f]alse statements of fact are particularly valueless; they interfere with the truthseeking function of the

marketplace of ideas"); *Herbert v. Landon,* 441 U.S. 153, 171 (1979) ("[s]preading false information in and of itself carries no First Amendment credentials"); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 771 (1976) (untruthful speech, commercial or otherwise, "has never been protected for its own sake"); *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 340 (1974) (no constitutional value in false statements of fact because they do not "materially advance [] society's interest in continued, robust and wide open debate").

Defendant attempts to get around the facts and the law by (1) framing his conviction as a content-based proscription of speech; (2) arguing that the statements here are constitutionally protected opinions; and (3) claiming that allowing his conviction to stand will chill "scientific" speech. These arguments are meritless.

First, the wire fraud statute does not regulate speech based on its content. The wire fraud statute applies to "any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises." 18 U.S.C. § 1343. While the First Amendment does not generally allow the government to restrict expression because of its subject matter, *United States v. Stevens*, 130 S. Ct. 1577, 1584 (2010), what the

wire fraud statute punishes is falsity, not a particular content or viewpoint. *See Renton v. Playtime Theaters, Inc.*, 475 U.S. 41, 48 (1986) ("content-neutral speech regulations" are "those that are justified without reference to the content of the regulated speech"); *McNeil*, 320 F.3d at 1040 (wire fraud statute punishes scheme to defraud). By contrast to the wire fraud statute, the statute in *Stevens*, which prohibited depictions of animal cruelty, was deemed a content-based prohibition. *See* 130 S. Ct. at 1584; *see also Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2663 (2011) (deeming law restricting pharmacies' sale, disclosure, or use of records that reveal the prescribing practices of individual doctors to be content-based).

Moreover, even if prohibitions on fraud were regarded as content-based, it would not follow that they are subject to strict scrutiny. To the contrary, the Supreme Court has made it clear that prohibitions on fraud are not subject to any First Amendment scrutiny at all. *See Stevens*, 130 S. Ct. at 1584 (fraud one of "limited areas" where the First Amendment "permit[s] restrictions upon the content of speech"); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 772 (1976) (same); *United States v. Nguyen*, Slip. op. 3359, 3371 (9th Cir. March 23, 2012) (statute proscribing intimidation is permissible content-based restriction). Thus, even if the wire fraud statute somehow amounts to a content-based prohibition on speech, it is nonetheless

constitutional. Were that not the case, no prosecution for perjury or fraud could ever withstand a First Amendment challenge.[20]

As to defendant's and amici's claim that the wire fraud statute may punish false statements of fact (such as misstating the number of deaths in a clinical trial), but not knowingly false statements of "opinion," that argument too is without merit.

First, there is no separate First Amendment privilege for opinions, and "expressions of 'opinion' may often imply an assertion of objective fact." *Milkovich v. Lorain Journal Co.*, 497 U.S. 1, 10, 18 (1990). Indeed, in *Milkovich*, the Supreme Court expressly declined to find such a privilege in the context of state defamation laws, concluding that existing constitutional safeguards were sufficient "without the creation of an artificial dichotomy between 'opinion' and fact." *Id.* at 10, 19.

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[20] *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002), is not to the contrary. *Conant* did not hold that a prosecution for knowingly false or fraudulent statements amounts to a content-based proscription. Indeed, *Conant* did not even involve false speech. *Conant* simply held that the district court properly enjoined the government from seeking to revoke doctors' licenses to prescribe controlled substances based solely on the doctors' professional recommendation of medical marijuana. *Id.* at 638. In so doing, this Court noted that the doctors' recommendation itself was not illegal conduct.

Second, the key statements at issue in the press release were not presented to the public as expressions of opinion, but were stated as demonstrable, reliable conclusions of fact. *See Campbell*, 897 F.2d at 1321 (rejecting argument that statement about availability of tax benefits was only an opinion and thus could not be false or fraudulent). The heading announced "Phase III Data Demonstrating Survival Benefit of Actimmune in IPF." ER 1906. The subheading read: "Reduces Mortality by 70% in Patients with Mild To Moderate Disease." ER 1906. The press release also offered a p-value that suggested statistical significance, without including information that revealed the unreliability of that conclusion. Moreover, the jury was instructed that they needed to find beyond a reasonable doubt that defendant made false or fraudulent statements and that a "statement is false or fraudulent if known to be untrue." SER 3330-31. Thus, the jury could not have found defendant guilty based on a statement the truth of which could not be known, like an opinion.[21]

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[21] In closing, defense counsel argued in part that to the extent others disagreed with the press release, it was simply a difference of opinion, not a violation of accepted rules, and thus could not be a basis for convicting defendant. SER 3402-03 ("There's just opinions, and differences of opinions"), 3447. The jury thus heard defendant's theory and rejected it.

Third, defendant's approach would immunize any knowingly false statement made with the intent to defraud so long as it involved a summary of the results, rather than the specific numbers. Under that approach, an individual could falsely describe a clinical trial as a success even if there were no favorable data, so long as he did not actually misstate the relevant numbers, because the statement would be opinion rather than fact. That approach simply makes no sense.

Finally, defendant lacks any basis for his conjecture that his conviction will chill legitimate speech, whether scientific or otherwise. Fraud requires a showing of knowledge of falsity and the specific intent to defraud and the jury was so instructed. *See McNeil*, 320 F.3d at 1040. For that reason, the only speech that will be "chilled" by this prosecution is the very fraudulent speech that receives no First Amendment protection.

"Laws directly punishing fraudulent speech survive constitutional scrutiny even where applied to pure, fully protected speech." *Commodity Trend Serv., Inc. v. CFTC*, 233 F.3d 981, 992 (7th Cir. 2000). There is no exception that applies whenever the mechanism of perpetrating the fraud happens to involve the deliberate distortion of the results of a scientific clinical trial. Moreover, a press release designed as a marketing tool is far from the sort of bona fide scientific and educational speech that appears in independent and peer-reviewed sources, such as

a journal article reprint or a medical textbook that defendant and his amici suggest will be chilled by his conviction.

2. Defendant is not being penalized for bona fide scientific speech

Defendant's and amici's claims that his conviction criminalizes genuinely held scientific opinions simply ignores the elements that the jury necessarily found beyond a reasonable doubt in convicting defendant, namely, that defendant knowingly made false or fraudulent statements with the intent to defraud. The wire fraud statute does not punish unorthodox views, false statements made in good faith, or even knowing lies, made without the intent to defraud. What it does permissibly cover are knowingly false statements made with the intent to defraud. *See Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620, 637 (1980).

Defendant and amici contend that the First Amendment prohibits criminalizing statements reflecting scientific judgment about which no clear scientific consensus has been reached. In light of the record in this case, that argument, which is not supported by the case law, is also factually incorrect.

First, although defendant called none of the expert witnesses he noticed, he asks that this Court reverse the jury's conviction based in part on declarations he introduced at the sentencing phase. AOB 45. To consider declarations submitted

after the fact by witnesses never cross-examined before the jury would encourage strategic sandbagging by counsel, who could choose to withhold witnesses rather than risk putting them on the stand.

Second, despite defendant's assertion, the statements in the press release were not merely debatable interpretation, but a fraudulent description of the trial results. The evidence brought in through the testimony of Drs. Walton, Fleming, Porter, and Crager established that the post-hoc subgroup analyses were inconclusive and unreliable, and that the subgroup's results conflicted with the results on pre-specified endpoints. By defendant's own earlier definitions, the trial was a failure. Moreover, there was no evidence that the clinical trial was being analyzed under some alternative theory.

3. Defendant's speech is entitled to even less protection if it is deemed commercial

Although the government can regulate knowingly false and fraudulent speech even if the speech would otherwise be fully protected, *Commodity Trend Serv., Inc.*, 233 F.3d at 992, defendant's speech was not pure scientific speech, but commercial speech. The speech at issue was commercial in nature because it was a press release that referred to a specific commercial product on the market, and was unquestionably disseminated for commercial benefit. ER 152. Moreover, the press release was used as a tool for marketing the drug to doctors and to patients.

Accordingly, there is even less reason for constitutional concern. As a general matter, "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity." *Central Hudson Gas & Electric Corp. v. Public Serv. Commission of New York*, 447 U.S. 557, 563 (1980).

In *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983), the Supreme Court explained that "[a]dvertisers should not be permitted to immunize false or misleading product information from government regulation simply by including references to public issues." *Id.* at 68. In *Bolger*, pamphlets from a condom manufacturer highlighting the importance of condom use – including one titled "Plain Talk about Venereal Disease" – were nonetheless found to be commercial because they advertised a specific product and were distributed with an economic motive. *Id.* at 62 n.4, 66-67. By the same token, defendant's press release retains commercial aspects notwithstanding its deceptive discussion of the results of a clinical trial.

Nor does *Mattel, Inc. v. MCA Records, Inc.*, 296 F.3d 894 (9th Cir. 2002), on which defendant relies, undercut this conclusion. *Mattel* was a trademark case, in which this Court held that a band's song spoofing Barbie did not infringe on Mattel's trademark. There, the speech was not purely commercial because it had

independent expressive value because it lampooned the Barbie image and was not just an advertisement. *Id.* at 907; *see also Hoffman v. Capital Cities/ABC, Inc.*, 255 F.3d 1180, 1185-86 (9th Cir. 2001) (holding that a doctored photograph in LA Magazine was not commercial speech, but that it would have been "[i]f the altered photograph had appeared in a Ralph Lauren advertisement"). Moreover, *Mattel* expressly recognized that the First Amendment does not protect fraud. 296 F.3d at 904.

Finally, defendant mistakenly asserts that his conviction cannot stand unless this Court concludes his speech is inherently misleading, as opposed to potentially misleading.[22] But even commercial speech that is merely potentially misleading may be regulated so long as the regulation directly advances a substantial state interest. *See Cent. Hudson Gas*, 447 U.S. at 566. Potentially misleading commercial speech about drug efficacy could encourage demand for drugs that are not beneficial for their intended uses, leading in turn to the prescription and use of drugs that are useless or harmful, and which physicians and patients would avoid (or at least would be able to avoid) if the speech were not misleading. For that

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[22] As to the general public, the speech was inherently misleading because the "possibilities for deception" were great and "the ability of the intended audience to evaluate the claims made" virtually nil. *Ass'n of Nat'l Advertisers, Inc. v. Lungren*, 44 F.3d 726, 731 (9th Cir. 1994) (internal quotations omitted); *see Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1108 (9th Cir. 2004).

reason, the government has a compelling interest in deterring the sort of fraudulent conduct in which defendant engaged. *Virginia Bd. of Pharmacy*, 425 U.S. at 772 (validating the government's interest in "insuring that the stream of commercial information flow cleanly as well as freely"); *see also Bd. of Trustees of the State University of New York v. Fox*, 492 U.S. 469, 475 (1989) (noting that to merit even the limited constitutional protection available for commercial speech, speech must concern lawful activity and not be misleading). Moreover, even if defendant's conviction is assumed to rest on speech that is merely potentially misleading, the jury found beyond a reasonable doubt that defendant acted with the intent to defraud. No case has ever held that a defendant who seeks to perpretrate a fraud and speaks with the affirmative intent of misleading his listeners, has a constitutional right to do so as long as his speech is merely potentially misleading.

III. THE GOVERNMENT PROVIDED FAIR NOTICE

A. Background

Post-trial, Harkonen argued that he was entitled to dismissal of the indictment or a judgment of acquittal because he was not given fair notice that the conduct he engaged in was criminal. CR 247. Acknowledging that "criminal statutes must provide explicit guidance regarding what is illegal and what is not," the district court nonetheless held that this case did not "implicate any vagueness

concerns." ER 58. The district court found that "the jury had before it sufficient evidence to conclude that Harkonen misrepresented the GIPF-001 results by stating that the data demonstrated a survival benefit when it, in fact, did not . . . ." ER 59. Furthermore, the district court concluded, defendant's "omission of the material fact that the data regarding the mild to moderate subgroup was derived from post-hoc analysis also subjected him to criminal liability." ER 59. In other words, the court held, the jury could have concluded that the press release's statements were objectively false, and not "open to any reasonable interpretation." The district court further held that: "[t]o contend that Harkonen was not on notice that if he lied in a press release about the success of a clinical trial for a drug that might have sales as high as $500 million per year is simply ludicrous." ER 59.

Defendant also argued that his Fifth Amendment rights were violated because no law or regulation other than the wire fraud statute placed him on notice that his conduct was criminal. The district court rejected this argument, noting that it depended upon a mischaracterization of the nature of defendant's crime. ER 59. The district court acknowledged that there was no law barring a company from reporting the results of a post-hoc subgroup analysis in a press release touting the results of a clinical trial. ER 59. "There is, however," the district court wrote, "a law – the wire fraud statute – that prohibits individuals from making

objective misrepresentations about clinical trial results and from omitting material facts about the nature of the analysis of those results with an intent to defraud." ER 59. Accordingly, the district court found that the wire fraud statute provided Harkonen with "more than sufficient notice about what was legal and what was illegal." *Id.*

B. Standard of Review

This Court reviews de novo questions of statutory interpretation. *United States v. Horvath*, 492 F.3d 1075, 1077 (9th Cir. 2007). Whether a statute is void for vagueness is a question of law reviewed de novo. *United States v. Cooper*, 173 F.3d 1192, 1202 (9th Cir. 1999).

C. A Reasonable Person Would Have Known That Making Knowingly False Statements About the Results of a Clinical Trial In a Press Release with the Intent to Defraud Could Result in Criminal Liability

Defendant argues that defendant could not have known that the statements in the press release would subject him to criminal liability. That argument is meritless.

Courts presume that a statute is constitutional. *Heller v. Doe*, 509 U.S. 312, 320 (1993). While laws must "give the person of ordinary intelligence reasonable opportunity to know what is prohibited, so that he may act accordingly," *Vill. of Hoffman Estates v. The Flipside*, 455 U.S. 489, 498 (1982), a statute must simply

be "intelligible, defining a 'core' of proscribed conduct that allows people to understand whether their actions will result in adverse consequences." *Forbes v. Napolitano*, 236 F.3d 1009, 1012 (9th Cir. 2000).

The wire fraud statute and the identical provision in the mail fraud statute, 18 U.S.C. § 1341, have repeatedly withstood challenges that they do not provide fair notice of the conduct prohibited. *See United States v. Frost*, 125 F.3d 346, 370 (6th Cir. 1997) (citing numerous cases rejecting vagueness challenges to the mail and wire fraud statutes). These statutes specifically prohibit a "core" of conduct, that is, a scheme to defraud people of money or property involving the mails or interstate wires. *See United States v. Bohonus*, 628 F.2d 1167, 1171 (9th Cir. 1980) ("Most mail fraud cases . . . [are] comprised of those schemes which deprive others of tangible property interests. There is no question that these types of schemes fall within the purview of the mail fraud statute."). That is precisely the sort of conduct the jury had to find here in order to convict defendant. Accordingly, the Supreme Court's decision in *Skilling v. United States*, 130 S. Ct. 2896 (2010), which narrowed the reach of the "honest services" provision of the

wire fraud statute, has, as the district court found, "absolutely no bearing on [defendant's] case."[23] ER 67.

Nor is it true that, as defendant argues at length, "the government must publish the criteria the criminal law will use to measure success [of a clinical trial]" for a conviction to stand. AOB 54. While there are any number of ways to commit fraud, including misrepresenting the results of a clinical trial to increase the sales of a drug, there is no requirement that federal law specifically prohibit the exact fraud scheme executed to give fair notice that that scheme is illegal. *Frost*, 125 F.3d at 370; *United States v. Green*, 592 F.3d 1057, 1064 (9th Cir. 2010) ("it is settled that wire fraud does not require proof that defendant's conduct violated a separate law or regulation, be it federal or state law").[24]

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[23] The same is also true of *McNally v. United States*, 483 U.S. 350 (1987), and *United States v. Bruchhausen*, 977 F.2d 464, 468 (9th Cir. 1992), both of which also concern honest services fraud. Those dealt with intangible rights, a far different cry from an attempt to sell a product based on misrepresentations about its efficacy.

[24] Nor is *United States v. Farinella*, 558 F.3d 695, 698 (7th Cir. 2009), to the contrary. The Seventh Circuit in *Farinella* reversed defendant's conviction for introducing a misbranded food into interstate commerce with the intent to defraud or mislead based on his sale of salad dressing after the "best when purchased by date." In so doing, the Seventh Circuit concluded that it was error to admit the testimony of an FDA employee that implied that FDA approval had to be obtained before changing the "best when purchased by date," where no statute or regulation required such approval. That case, however, does not require that there be a statute or case specifically precluding the particular conduct at issue.

Moreover, defendant's argument that he did not have fair notice that he might be committing wire fraud because the statements he made in the press release were part of an "evolving scientific debate" simply ignores the evidence showing that defendant did not engage in good faith scientific debate, but instead lied about the GIPF-001 trial results and Actimmune. As detailed in Part I, the government presented extensive evidence of a scheme to defraud, including that (1) the press release was false and fraudulent because it presented as a firm conclusion something that was unreliable and inconclusive; (2) defendant knew the press release was false and fraudulent when he drafted it because he had been repeatedly warned about the limitations of the post-hoc analyses and because he excluded from the drafting process the people who knew those limitations; and (3) defendant put out the press release with the intent to defraud others by falsely and fraudulently portraying the trial results as proving that Actimmune was an effective treatment for IPF.

Finally, wire fraud is a specific intent crime. To convict defendant, the government was required to prove that he had an intent to defraud, that is, that he intended to commit fraud by putting out statements that he knew were false or fraudulent and that he knew would induce people to part with their money. This intent requirement undermines any claim that defendant did not have fair notice of

what the wire fraud statute outlawed. *See United States v. Conner*, 752 F.2d 566, 574 (11th Cir. 1985) ("The requirement that the act must be willful or purposeful . . . does relieve the statute of the objection that it punishes without warning an offense of which the accused was unaware.") (quoting *Screws v. United States*, 325 U.S. 91, 102 (1945)); *Frost*, 125 F.3d at 370 ("[t]he broad language of the statute, intended by Congress to be sufficiently flexible to cover the wide range of fraudulent schemes mankind is capable of devising," not unconstitutionally vague given the statutory requirement that the defendant act willfully and with specific intent to defraud). Because the jury here had to find both knowledge and intent to defraud, there is no fair notice problem.

IV. THE DISTRICT COURT CORRECTLY INSTRUCTED THE JURY

A. Background

At trial, defendant requested a two-page, single-spaced good faith instruction. ER 2671-72. Among other things, the instruction provided that "the good faith of Defendant W. Scott Harkonen is a complete defense to the charges of fraud . . . because the defendant's good faith is fundamentally inconsistent with the intent to defraud by means of false or fraudulent pretenses, representations, or promises as alleged in the wire fraud charge . . ." ER 2671. It also stated that "mere puffing, exaggerated enthusiasm, and high-pressure salesmanship do not

constitute fraud provided such statements simply magnifies [sic] an opinion of the advantages of a product without falsely asserting the existence of qualities the product does not possess." ER 2671. The instruction also included directives that the jury consider all of the evidence in the case going to defendant's state of mind, that the burden of proof was on the government, and that the jury had to find the elements beyond a reasonable doubt, all of which were covered by other instructions. *Id.*

The court denied defendant's request, concluding that the instructions on intent adequately covered defendant's good faith claim, and pointed out that this was a proper subject for argument. SER 3294-96.

The court instructed the jury in relevant part that to convict defendant of wire fraud, it had to find that:

> First, defendant made a scheme or plan to defraud by making false or fraudulent statements, with all of you agreeing on at least one false or fraudulent statement that was made. False or fraudulent statements may include deceitful statements, half-truths, or statements which omit material facts. A statement is false or fraudulent if known to be untrue or made with wanton or reckless disregard for its truth or falsity and made with the intent to deceive.
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> Second, defendant knew that the statements made in the August 28, 2002 press release were false or fraudulent at the time they were made.

> Third, the statements were material; that is, they had a natural tendency to influence, or were capable of influencing, a person to part with money or property. It is not necessary for the government to prove that the scheme was successful, that defendant actually realized any gain from the scheme, or that an intended victim actually suffered any loss.
>
> Fourth, defendant acted with the intent to defraud.
>
> Fifth, defendant used, or caused to be used, the interstate wires to carry out or attempt to carry out the scheme.

SER 3330-32. The district court also gave a separate instruction with respect to intent to defraud: "[t]o act with 'intent to defraud' means to act knowingly with the specific intent to deceive or cheat, ordinarily for the purpose of either causing some financial loss to another, or bringing about some financial gain to one's self." SER 3336.

B. Standard of Review

In determining whether the court's jury instructions were proper, this Court considers "whether the instructions – taken as a whole and viewed in context of the entire trial – were misleading or confusing, inadequately guided the jury's deliberations, or improperly intruded on the fact finding process." *United States v. Beltran-Garcia*, 179 F.3d 1200, 1205 (9th Cir. 1999). "A defendant is entitled to have the judge instruct the jury on his theory of defense, provided that it is

supported by law and has some foundation in the evidence." *United States v. Crandall*, 525 F.3d 907, 911 (9th Cir. 2008) (internal quotation omitted). However, "it is not reversible error to reject a defendant's proposed instruction on his theory of the case if other instructions, in their entirety, adequately cover that defense theory." *Id.* at 912 (internal quotation omitted). Whether the proposed instruction is supported by law is reviewed de novo. *Id.* at 911. Whether the jury instructions adequately covered the defense's theory of the case is likewise reviewed de novo. *United States v. Romm*, 455 F.3d 990, 1002 (9th Cir. 2006).

C. Argument

As defendant acknowledges, AOB 69, n.26, in general, this Court does not require a good faith instruction so long as the court correctly instructs the jury on mens rea. *See United States v. Shipsey*, 363 F.3d 962, 967 (9th Cir. 2004); *United States v. Sarno*, 73 F.3d 1470, 1487 (9th Cir. 1995); *United States v. Solomon*, 825 F.2d 1292, 1297 (9th Cir. 1987). Because defendant does not contend on appeal that the district court erred in instructing the jury on intent to defraud, that should be the end of the matter. *See Shipsey*, 363 F.3d at 967 ("Our case law is well settled that a criminal defendant has 'no right' to any good faith instruction when the jury has been correctly instructed" with regard to intent).

Defendant argues, however, that the failure to give the puffery language in his good faith instruction warrants reversal. Specifically, he argues, this Court's decisions in *United States v. Tarallo*, 380 F.3d 1174, 1191-92 (9th Cir. 2004), *United States v. Amlani*, 111 F.3d 705, 711 (9th Cir. 1997), and *United States v. Gay*, 967 F.2d 322, 329 (9th Cir. 1992), require that a puffery instruction be given unless the jury is instructed on good faith. He is wrong. The cases he cites simply rejected challenges based on the failure to give a puffery instruction because the other instructions (in those cases, good faith) adequately covered the issue. None of those cases stand for the proposition that only a good faith instruction will compensate for the failure to give a puffing instruction.

Here, the jury was instructed that to convict it had to find that the statements were false. A puffing defense does not include false assertions, only exaggerated ones. *Amlani*, 111 F.3d at 717-18. Indeed, defendant's own proposed instruction acknowledged this fact. ER 2671 (excluding "false[] assert[ions]" about "the existence of qualities the product does not possess"). In other words, because the jury was instructed that it was required to find false or fraudulent statements, it could not have convicted if it concluded that defendant was merely exaggerating the results.

Moreover, the instruction proposed by defendant was lengthy and redundant in light of the court's other instructions. *Id.* In particular, it repeated elements of the instructions on reasonable doubt, burden of proof, and what evidence to consider. *Id.* Accordingly, the district court did not abuse its discretion by declining to give defendant's proposed instruction.[25]

V. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN DENYING DEFENDANT'S MOTION FOR A NEW TRIAL

A. Background

1. The VA Documents

Prior to trial, the government produced approximately 370,000 documents from, among other entities, the FDA, the SEC, and the VA. ER 20. After defendant's trial, the government produced 67 pages of VA documents that had not previously been turned over. ER 20. The documents fell into four categories: (1) three letters from one VA regional unit, explaining that the relevant clinical data at the time did not support the use of Actimmune to treat IPF (one letter mentioned the August 2002 press release and stated that the press release was not sufficient scientific evidence of the drug's efficacy); (2) an October 17, 2002,

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[25] Even if the district court's ruling was error, any error was harmless in light of the evidence of and instructions on falsity, knowledge, and intent to defraud.

memorandum from the Chair of the Formulary Subcommittee for that same region indicating that the current evidence was insufficient to support the use of the drug (and incorrectly mentioning the September 18, 2002, press release as the first public release about GIPF-001); (3) guidelines from two other VA regional units indicating when it is appropriate to prescribe Actimmune (one document predated the press release, and the other postdates it by about six years); and (4) meeting minutes for the Pharmacology Benefits Medical Advisory Groups for two VA regional groups.[26] ER 20-22.

Defendant argued that the belated production of these documents warranted a new trial. The district court rejected that claim, holding that "[i]n light of the substantial evidence of materiality presented at trial, the minimal probative value of the VA documents, and their cumulative nature, the suppression of the VA documents does not reasonably undermine confidence in the jury's verdict." ER 31.

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[26] The August 2002 press release is not mentioned in any of those minutes. One set of minutes, from September, October, and November 2002, stated that the groups considered Actimmune experimental and not for use unless enrolled in clinical trials. ER 20-22. The other set included meetings on July 2003 and May 2007. *Id.* The 2003 notes indicated that while they did not promote the use of Actimmune, they would permit it if all other treatments were exhausted. *Id.* The 2007 notes indicated that Actimmune was no longer allowed for IPF, apparently based on the negative results of another clinical trial announced a few months earlier. *Id.*

2. The Amicus Brief

On November 12, 2010, more than a year after defendant's conviction, the United States filed an amicus brief in the Supreme Court in *Matrixx Initiatives v. Siracusano*, No. 09-1156. The respondents had brought a securities fraud class action lawsuit against Matrixx, the publicly-traded manufacturer of Zicam, an over-the-counter cold remedy, claiming that Matrixx had failed to disclose to the public information about customers who had lost their sense of smell. Despite being aware of a clinical trial revealing that a small number of customers had experienced this side effect, Matrixx continued to market its drug and publicly extol the company's growth potential. *Matrixx Initiatives v. Siracusano*, 131 S. Ct. 1309, 1314-16 (2011).

When reports of this side effect surfaced, however, Matrixx's stock price dropped. *Id.* The district court granted Matrixx's motion to dismiss, holding that the plaintiffs had not alleged a statistically significant correlation between the use of Zicam and the loss of smell so as to make the failure to disclose complaints and the clinical trial in question a material omission. *Id.* at 1317. This Court reversed, holding that there are no bright line rules for determining materiality under SEC Rule 10b-5. *Id.*; *Siracusano v. Matrixx Initiatives*, 555 F.3d 1167, 1178 (9th Cir. 2009). The Supreme Court granted certiorari and affirmed. 131 S. Ct. at 1317.

In its amicus brief to the Supreme Court, the government agreed with this Court's decision, and argued that statistical significance is not the only relevant measure of the materiality of "adverse event" reports. The government also contended that causation can appropriately be inferred through consideration of multiple factors, independent of statistical significance, and in a footnote noted that the same principle applies to studies suggesting a particular drug is efficacious, noting that a clinical trial could "generate meaningful interest" even if the results were not statistically significant. ER 23.

The Supreme Court's opinion cited to and adopted the government's arguments in its amicus brief, holding, among other things, that a lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events. *See, e.g., Matrixx*, 131 S. Ct. at 1319-20.

Defendant moved for a new trial based on "newly discovered evidence in the form of the government's amicus brief in *Matrixx*," claiming that because the government argued in *Matrixx* that statistical evidence was not the only reliable indication of causation, it could not argue here that statistical principles alone precluded any reasonable conclusion that Actimmune caused a reduction in death. CR 247.

The district court denied defendant's motion, concluding that (1) the brief was not "newly discovered evidence," but argument, (2) defendant "amply pursued arguments regarding the potential meanings of statistical significance – and debates surrounding p-values more specifically – during cross-examination," and (3) defendant was not entitled to a new trial in light of the Supreme Court's decision. ER 32. "*Matrixx* has little bearing on the issues presented in this case, and to the extent the decision is relevant, it is entirely consistent with the theory pursued by the government." *Id.*

B. Standard of Review

This Court reviews a district court's decision on a motion for a new trial for abuse of discretion. *United States v. Shaffer*, 789 F.2d 682, 687 (9th Cir. 1986).[27]

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[27] Normally, the inquiry under Rule 33 is whether new evidence indicates that a new trial would probably result in an acquittal. *United States v. Harrington*, 410 F.3d 598, 601 (9th Cir. 2005). Defendant argues, however, that his claims regarding the amicus brief should be reviewed under a *Brady* standard, thus whether it could "reasonably be taken to put the whole case in such a different light as to undermine confidence in the verdict." AOB 74; *see United States v. Bagley*, 473 U.S. 667, 677 (1985). Because nothing about the amicus brief, or the positions taken in it, amount to the knowing presentation of false testimony or the suppression of exculpatory evidence, this Court reviews the district court's assessment of whether the new "evidence" would probably result in an acquittal, and not whether it could reasonably be taken to put the case in such a different light as to undermine confidence in the result.

C. The VA Documents Do Not Undermine Confidence in the Jury's Verdict

Defendant argues that the VA documents would have been vital to demonstrating the press release's lack of materiality because they show that the VA's decision whether to prescribe Actimmune for IPF was based on independent medical evaluations, in which "[c]ompany conclusions in press releases had no role to play." AOB 66. Because the evidence at trial of materiality was "substantial," and because the VA documents were both minimally probative and cumulative in nature, this Court should affirm defendant's conviction.

A *Brady* violation has three components: (1) the evidence at issue must be favorable to the accused; (2) the evidence must have been suppressed either willfully or inadvertently by the government; and (3) defendant must have been prejudiced. *United States v. Kohring*, 637 F.3d 895, 902 (9th Cir. 2011). There is a reasonable probability of prejudice when suppression of evidence undermines confidence in the result of the trial. *Id.* The evidence in question is considered collectively, and if it is merely cumulative, then the failure to disclose is not a violation. *Id.* Defendant cannot demonstrate that reversal is warranted under this standard.

First, as to their exculpatory nature, the government need not show that anyone in fact relied on the false statements in the press release to show materiality for purposes of a wire fraud violation. *Jenkins*, 633 F.3d at 802 n.3. Thus, the fact that some of the VA documents do not affirmatively show that doctors actually relied on the press release to prescribe Actimmune simply means that the documents do not affirmatively support that the VA doctors relied on the press release in assessing whether to prescribe the drug. That does not mean, however, that the documents were exculpatory because actual reliance is not an element of the offense.

Second, although convincing doctors to prescribe Actimmune was a central part of defendant's scheme, the marketing efforts around the press release were not limited to pulmonologists, but targeted patients and pharmacies as well. Thus, even if defendant could argue on the basis of these documents that certain VA pulmonologists disregarded the August 2002 press release, as the district court noted, "this would not undermine the materiality of the misrepresentations to the full audience the company tried to influence." ER 26.

As the district court also found, the documents held "very little, if any, exculpatory value for [defendant], and taken cumulatively the documents fail to cast any serious doubt as to the materiality of the statements at issue here." ER

26-27. The only VA document to mention the press release shows that it was at least partly responsible for a patient's request for Actimmune. ER 2916. In that letter, the VA declines the request from the son of an IPF patient that his father be prescribed Actimmune, and concludes that the press release does not provide sufficient scientific evidence. ER 2916. While the letter may marginally undermine the conclusion that the press release influenced the decision of one doctor, as the letter makes clear, the patient's son actually cited the press release when requesting that Actimmune be prescribed. ER 2916. Thus, the press release clearly influenced the VA patient or his son. ER 27.

Finally, the October 17, 2002, memorandum from the Chair of the Formulary Subcommittee raises an inference that the author was unaware of the August 28, 2002, press release and even "appears to buttress the materiality of the misrepresentations made in the August 2002 press release because it focused on the specific details of the GIPF-001 trial" – the same type of details omitted in the 2002 release. ER 28, 2929-30. Furthermore, the author did look to a press release for data on the clinical trial, noting that there was no additional information available to use in evaluating the clinical trial. ER 2929-30. Given this record, defendant cannot demonstrate that he was prejudiced by the late discovery of these marginally relevant VA documents.

D. The Government's Amicus Brief in *Matrixx* Does Not Warrant a New Trial

Defendant argues that (1) the *Matrixx* brief, which was filed more than a year after defendant's conviction, contains admissions that conflict with the government's position in this case; (2) those admissions were material to the issues of falsity, knowledge of falsity, and good faith; and (3) that the admissions were prejudicial. The district court did not abuse its discretion in rejecting those claims.

First, even assuming the *Matrixx* brief was "evidence," in order to warrant a new trial, this new "evidence" must be neither cumulative nor merely impeaching. *United States v. Kulczyk*, 931 F.2d 542, 548 (9th Cir. 1991). As the district court found, defendant "amply pursued arguments regarding the potential meanings of statistical significance – and debates surrounding p-values more specifically – during cross-examination," ER 32, and thus the *Matrixx* brief would have added nothing to the quality of his defense.

Second, as the district court also found, defendant seeks to reframe the critical issue of his intent into an inquiry whether there was a good faith reason to believe that Actimmune in fact conferred survival benefits, when that was not the issue presented to the jury. The question presented by this case is whether the August 2002 press release misrepresented the results of the GIPF-001 trial in a

material way. "If Harkonen has a good faith basis for concluding that Actimune was an effective treatment for IPF based on a number of factors outside the GIPF-001 trial results, he could have made those connections in the press release and this would be a very different case." ER 34. Put another way, if defendant had made a case that there were reasons other than the statistical analysis performed by InterMune to believe that Actimmune was an effective treatment, he could have done so. What he could not do was to present that analysis in a false and fraudulent manner.

Third, saying that statistically insignificant data does not refute an inference of causation is not the same as saying that it gives rise to such an inference. Put another way, "[i]t may certainly be relevant to physicians that there is non-statistically significant data showing survival benefits for IPF patients, but as the evidence showed at trial, such data on its own does not establish the touted relationship." ER 33. Thus, while the *Matrixx* brief correctly observed that causation is not simply established through statistical results, it does not hold that one may knowingly misrepresent those results to establish an otherwise lacking causal link.

VI. THE DISTRICT COURT ERRED IN ITS CALCULATION OF HARKONEN'S ADVISORY SENTENCING GUIDELINES RANGE

A. Background

1. The Presentence Report

The Presentence Report calculated defendant's offense level using U.S.S.G. § 2B1.1.[28] Section 2B1.1 provides for a base offense level of 6. PSR ¶ 29. The Presentence Report also included a 22-level enhancement based on amount of loss, pursuant to U.S.S.G. § 2B1.1(b)(1)(L), and an additional 12 levels based on a number of enhancements – including, in relevant part, one because defendant knew or should have known that a victim of the offense was a vulnerable victim, pursuant to U.S.S.G. § 3A1.1(b)(1), and one because the offense involved a large number of vulnerable victims, pursuant to U.S.S.G. § 3A1.1(b)(1) and (2). PSR ¶ 30-31.

The Probation Office "believe[d] it would be impossible to determine an actual loss, but to insist that there was no intended loss would be disingenuous." PSR ¶ 30. It found that the government's estimation of intended loss as $32.1 million was "consistent with the trial testimony." *Id.* The Probation Office

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[28] Because of *ex post facto* issues, the Probation Office used the Nov. 2001 edition of the Sentencing Guidelines. U.S.S.G. § 1B.1.11(b)(1).

observed that in addition to any possible altruistic wishes, defendant's crime was "clearly motivated by a desire to perpetuate the use and sale of Actimmune." *Id.*

The Probation Office also concluded that the victims (IPF patients) were unusually vulnerable due to their physical condition, and that defendant should have known about this. PSR ¶ 33. More specifically, the Probation Office cited "[t]he marketing of a drug [that] was an ineffective cure for a fatal disease," and the fact that victims were allegedly given "a false hope that the drug would work, when in fact, the clinical trial had failed." PSR ¶ 33. Although there is no definition of what constitutes a large number of victims, the PSR noted that there were approximately 200,000 patients suffering from IPF at the time of the press release. PSR ¶ 30.[29]

2. The Government's Position on Loss

In its initial briefing, the government provided an intended loss calculation of $32.1 million. SER 3784. The government limited the loss to 2003, when Harkonen left InterMune, and based it on Harkonen's stated intent that

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[29] In an addendum to the PSR, the Probation Office responded to defendant's objections to, among others, the amount of loss and vulnerable victim enhancements. The Probation Office acknowledged that actual loss was difficult to determine, but noted that "that does not mean that the actual loss is zero." PSR Add. at 2. The Probation Office noted defendant's position that there were no victims because there was no actual loss, but did not resolve the objection.

Actimmune sales double. *Id.* If Actimmune's quarterly sales had remained what they were in the third quarter of 2002 ($28.5 million), the intended loss between the fourth quarter of 2002 and the second quarter of 2003 was $32.1 million. *Id.*

Subsequent briefing noted that the evidence could support a larger intended loss amount. Specifically, Harkonen predicted in his presentation to the InterMune board of directors that if the Phase III trial failed, sales would, at best, remain flat ($90-$100 million per year). CR 304. Rounding sales up, they would have been approximately $100 million a year. *Id.* Harkonen projected that if the GIPF-001 trial produced equivocal results, Actimmune sales would be $130 million in 2003, $160 million in 2004, reaching peak sales of $450 million in 2007. *Id.* If the Phase III trial produced positive results, Actimmune sales were projected to be $180 million in 2003, $300 million in 2004, and reaching peak sales of $750 million in 2007. *Id.*

Eight days after the press release, Harkonen gave a presentation to investors at the BioCentury Newsmakers Conference, which showed that he intended the press release to push sales to $200 million in 2003, and $400 million in 2004. *Id.* Even assuming Harkonen believed the results to be equivocal, according to his own projections, Actimmune sales should only have been $130 million in 2003, and $160 million in 2004. Therefore, Harkonen's intended loss for 2003 was $70

million (*i.e.*, $200 million minus $130 million), and the intended loss for 2004 was $240 million (*i.e.*, $400 million minus $160 million), for a combined total of $310 million. *Id.*

The government also provided three alternative calculations of actual loss: $22.3 million, $1.4 million, and $50,000. *Id.* The first was the result of subtracting estimations of what sales would have been but for the false press release from actual sales, the second was the result of taking the increase in sales and subtracting from it the amount of growth that could have been expected using historical growth patterns, and the third, at a bare minimum, was the cost of a year's worth of a single prescription. *Id.*

3. The Sentencing Hearing

The district court sentenced Harkonen on April 13, 2011. It found that the base offense level was 6. SER 3711. While it might be "common sense" to attribute the increase in Actimmune sales following the issuance of the press release to the fraudulent statements in the press release, the court concluded it was "just, you know, speculation," because those who prescribed and purchased Actimmune could have done so for various reasons. *Id.* In fact, because IPF was a fatal disease, the court surmised that patients would have taken Actimmune regardless of the press release. *Id.* The district court stated that "there was some

positive extrapolation that could [be] made [from the Phase III trial results] albeit not in the manner that was done in the press release," which could have accounted for the increase in Actimmune sales. SER 3675. "So it could as easily be that doctors were extrapolating from the data without regard to the hype that this was a good idea to prescribe . . . ." SER 3675-76. After concluding that there was no way to determine an actual loss, the district court failed to address the issue of intended loss.

The district court also declined to enhance the offense level for vulnerable victims under U.S.S.G. § 3A1.1(b)(1) because it imported the U.S.S.G. § 2B1.1 definition of a victim "as someone who suffered an actual loss." SER 3712. Because the court found no actual loss, it found there were no actual victims. *Id.*; *see id.* at 3653-56.

B. Standard of review

This Court reviews de novo the district court's interpretation of the Sentencing Guidelines. *United States v. Yepez*, 652 F.3d 1182 (9th Cir. 2011). It reviews the district court's factual findings at sentencing for clear error, and its application of the Sentencing Guidelines to the facts for abuse of discretion. *Id.* A district court abuses its discretion when it makes an error of law or does not apply the correct law. *See Koon v. United States*, 518 U.S. 81, 100 (1996).

C. The District Court Erred in Failing to Consider Intended Loss

The district court legally erred by failing to consider the amount of intended loss. "The Guidelines require a district court to calculate the amount of loss caused by fraud, and correlate the severity of the sentence to the amount of the loss." *United States v. Treadwell*, 593 F.3d 990, 1000 (9th Cir. 2010). Loss is the greater of actual or intended loss. U.S.S.G. § 2B1.1 cmt. n.2(A) (2001). Actual loss is the "reasonably foreseeable pecuniary harm that resulted from the offense," that is, monetary harm defendant knew, or reasonable should have known, was a potential result of the offense. U.S.S.G. § 2B1.1 cmt. n.2(A)(i), (iii), & (iv). Intended loss is the pecuniary harm that was intended to result from the offense, even if what was intended "would have been impossible or unlikely to occur." U.S.S.G. § 2B1.1 cmt. n.2(A)(ii). "The court need not make its loss calculation with absolute precision; rather, it need only make a reasonable estimate of the loss based on the available information." *United States v. Zolp*, 479 F.3d 715, 719 (9th Cir. 2007); *see Treadwell*, 593 F.3d at 1003; U.S.S.G. § 2B1.1 cmt. n.2(C).

Here, however, after concluding that it could not determine actual loss with sufficient specificity, the district simply failed to consider intended loss. That was legal error given that the government had advanced a convincing theory of intended loss adopted by the Probation Office. *Cf. United States v. Bonner*, 522

F.3d 804, 808 (7th Cir. 2008) (district court "supposed to consider intended loss"); *United States v. Hamaker*, 455 F.3d 1316, 1337 (11th Cir. 2006) (district court required to make independent findings as to loss despite jury findings).

Indeed, even if the district court's ruling is viewed as an implicit rejection of the government's theory of intended loss, the court still had a responsibility to determine loss independently. Here, the evidence showed that Harkonen intended the fraudulent statements in the press release to lead to greater sales of Actimmune. By his own revenue forecasts, the negative results of the Phase III trial should have led to a flat-lining in Actimmune sales at $100 million in 2003 and 2004. After the press release was issued, he told investors at the BioCentury Newsmakers Conference that the GIPF-001 trial results would lead to Actimmune sales of $200 million in 2003 and $400 million in 2004. Even if the court assumed that Harkonen reasonably believed that the Phase III trial results were equivocal, rather than negative, by Harkonen's revenue forecasts, equivocal results should have lead to Actimmune sales of $130 million in 2003 and $160 million in 2004, rather than the $200 million in 2003 and $400 million in 2004 that defendant predicted in the press release.

The district court's finding of no loss rested on the idea that it was impossible to determine whether doctors had prescribed Actimmune based on the press release. But intended loss is the pecuniary harm that was intended to result from the offense, even if that would have been impossible or unlikely to occur. *United States v. Tulaner*, 512 F.3d 576, 578 (9th Cir. 2008). In *Tulaner*, the defendant fraudulently ordered twelve sputting discs from JMI, intending to steal all twelve. *Id.* The fact that JMI was only willing to ship four discs at a time did not limit the intended loss to the four discs that the defendant received. *Id.* In this case, the fact that the defendant intended the press release to increase Actimmune prescriptions was sufficient to make an intended loss finding, whether or not it had the intended consequence. And, in fact, the intended loss here (*i.e.*, Harkonen's projections) closely matched the actual consequences. Accordingly, the district court erred in not determining intended loss.

D. The District Court Legally Erred in Refusing to Add Two Points for Vulnerable Victims

U.S.S.G. § 3A1.1(b)(1) requires a district court to increase defendant's offense level by two if defendant knew or should have known that a victim of the offense was a vulnerable victim. The application notes define a vulnerable victim as a person who "is a victim of the offense of conviction and" any relevant

conduct under U.S.S.G. § 1B1.3, and "who is unusually vulnerable due to age, physical or mental condition, or who is otherwise particularly susceptible to the criminal conduct." U.S.S.G. § 3A1.1 cmt. n.2. The application note explains that it should apply, "for example, in a fraud case in which defendant marketed an ineffective cancer cure . . . in which defendant selected a handicapped victim." *Id.*

An element of wire fraud is that defendant participated in a scheme to defraud. *United States v. Ciccone*, 219 F.3d 1078, 1083 (9th Cir. 2000). While the fraud need not have succeeded, defendant must have had the intent to defraud. *See Treadwell*, 593 F.3d at 996 (noting that Section 1343 requires proof that defendant intended to defraud "victim," to "deprive another" of money or property by means of false or fraudulent pretenses, representations or promises" without necessarily having intended to cause victim pecuniary loss (internal quotation and citation omitted)); *Tulaner*, 512 F.3d at 580 ("A wire fraud conviction does not require proof that defendant's actions caused the harm the scheme sought to inflict.").

Here, the government argued that the patients were unquestionably vulnerable victims given that they had been diagnosed with a fatal disease with no known cure. SER 3788-90. Harkonen knew that these patients were vulnerable, and intended the press release to be read by patients and their families. SER 3790.

Nevertheless, the district court refused to apply the vulnerable victim enhancement, finding that a victim for purposes of the enhancement had to be more than the object of the scheme to defraud, but a victim who suffered an actual loss as defined in a separate Guideline, U.S.S.G. § 2B1.1. SER 3712. Because the district court found that there was no actual loss, it found there were no victims. *Id.*

That was error. While U.S.S.G. § 2B1.1 defines a victim as one who has suffered "actual loss," it also expressly provides that its application notes apply "for purposes of *this* guideline." (emphasis added). The vulnerable victim provision, U.S.S.G. § 3A1.1, by contrast, includes no definition of "victim."

Other Circuits have addressed the question of whether a "vulnerable victim" of a fraud crime under U.S.S.G. § 3A1.1 must also qualify as a "victim" under U.S.S.G. § 2B1.1. Those Circuits are unanimous in holding that Section 2B1.1's definition of victim does not limit Section 3A1.1. *See United States v. Salahmand*, 651 F.3d 21, 26-29 (D.C. Cir. 2011) ("§ 2B1.1's definition of 'victims' does not govern increases under § 3A1.1"); *United States v. Kennedy*, 554 F.3d 415, 423-24 (3d Cir. 2009) ("The Guidelines make clear that 'victims' under § 2B1.1 and § 3A1.1(b) are separate definitions. . . . we are not bound by the definition of 'victim' in § 2B1.1, to determine the applicability of U.S.S.G. § 3A1.1(b)"); *cf.*

United States v. Stewart, 33 F.3d 764, 770 (7th Cir. 1994) ("There is no requirement in Section 3A1.1 that a target of defendant's criminal activities must suffer financial loss.").

Indeed, the Sentencing Commission itself has indicated that the reach of the phrase "victim of the offense" in Section 3A1.1 is broader than the victim of the offense of conviction. *See* U.S.S.G. App. C, Amdt. 564 ("'victim of the offense' in § 3A1.1 . . . refers . . ., more broadly, to a victim of any relevant conduct"); *see also United States v. Haggard*, 41 F.3d 1320, 1326 (9th Cir. 1994) (holding that "courts properly may look beyond the four corners of the charge to defendant's underlying conduct in determining whether someone is a 'vulnerable victim' under Section 3A1.1. By the words of the provision itself, no nexus is required between the identity of the victim and elements of the crime charged."). If the victim of a crime for purposes of Section 3A1.1 does not necessarily have to be a victim of the charged crime, then the victim of 18 U.S.C. § 1343 for purposes of Section 3A1.1 would include those victims defendant intended to defraud and not only those defined as victims for separate purposes under Section 2B1.1 (*i.e.*, those

who sustained actual loss as a result of defendant's fraud).[30] Accordingly, this Court should reverse defendant's sentence and remand for resentencing.

CONCLUSION

For the reasons set forth above, defendant's conviction should be affirmed, and this case should be remanded for resentencing.

DATED: March 30, 2012

Respectfully submitted,

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Acting under authority conferred by
28 U.S.C. § 515

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[30] Further undermining the district court's interpretation is Section 2B1.1's provision that the vulnerable victim enhancement shall not apply if the offense involved 50 or more victims, defined as those sustaining an actual loss. U.S.S.G. § 2B1.1 cmt. n.4(D). No conflict exists where the offense involved 10 to 49 victims or was committed through mass-marketing.

STATEMENT OF RELATED CASES

Pursuant to Rule 28-2.6(a) of the United States Court of Appeals for the Ninth Circuit, counsel for Plaintiff-Appellee states that the government is not aware of any related cases.

Date: March 30, 2012

/s/ Anne Voigts
ANNE M. VOIGTS
Assistant United States Attorney

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32 (a)(7)(c) and Circuit Rule 32-1, I certify that:

_X_ Pursuant to Fed. R. App. P. 32 (a)(7)(B)(I) and Ninth Circuit Rule 32-1, the attached answering brief is:

_X_ Proportionately spaced, has a typeface of 14 points or more and contains 21,320 words; or,

___ Monospaced, has 10.5 or fewer characters per inch, and contains ___ words.

Date: March 30, 2012

/s/ Anne Voigts
ANNE M. VOIGTS
Assistant United States Attorney

CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2012, I electronically filed the Government's Brief in the case of *United States v. Harkonen,* CA Nos. 11-10209, 11-10242, with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the cases are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

I also certify that on the same day the **Government's Supplemental Excerpts of Record (Volumes 1 to 20)** were served to the party or parties listed below via Federal Express service:

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Counsel for Petitioner
W. SCOTT HARKONEN

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

W. SCOTT HARKONEN, Petitioner, v. UNITED STATES OF AMERICA, Respondent.	Case No. CR 08-0164 MHP **DECLARATION OF DENNIS P. RIORDAN IN SUPPORT OF PETITION FOR WRIT OF CORAM NOBIS**

I, Dennis P. Riordan, declare under penalty of perjury that:

1. I am licensed to practice law in all state and federal courts of California.

2. I am lead counsel for petitioner Doctor Scott Harkonen in this coram nobis action.

3. I did not represent Dr. Harkonen during trial proceedings in this court between his indictment in 2008 and sentencing in April of 2011.

4. Following sentencing, I was retained by Dr. Harkonen to serve as a consultant on his direct appeal of his conviction to the Ninth Circuit, in which the government also took a cross-appeal of Dr. Harkonen's sentence. I was not responsible for reviewing the record on appeal, or drafting the briefs submitted to the Court of Appeals, although I did review them and make suggestions to Dr. Harkonen's lead counsel on appeal, Mark Haddad of the Sidley Austin firm.

Attorney Haddad presented oral argument for Dr. Harkonen in the Circuit in December of 2012.

5. During the Ninth Circuit proceedings, the government requested and received extensions of time to file its answering brief on Dr. Harkonen's direct appeal totaling 98 days. It requested and received an additional 38 days to file its reply brief on its cross-appeal of Dr. Harkonen's sentence.

6. I did not author Dr. Harkonen's certiorari petition, which was filed by attorney Haddad in the Supreme Court on August 5, 2013. The government requested and received extensions of 60 days to file its Opposition to Dr. Harkonen's petition, which was denied by the Supreme Court on December 16, 2013.

7. In 2012, during the course of the Ninth Circuit appeal, I was retained by Dr. Harkonen to represent him at proceedings to revoke his medical license before the California Medical Board. I represented him at a hearing before an Administrative Law Judge in November of 2012, as well as on his appeal to the Board itself of the judge's proposed decision to revoke his medical license decision solely on the basis of his federal fraud conviction. Following the Board's denial of that appeal, I also represented Dr. Harkonen on writ proceedings in the San Francisco Superior Court. On August 26, 2013, 2013, the Superior Court vacated the Board's decision on the ground that the ALJ and Board had denied Dr. Harkonen due process of law by refusing to consider the evidence he had proffered in his defense before the ALJ.

8. The Superior Court remanded the matter to the Medical Board, which in turn remanded the matter to the Administration Law Judge for rehearing. Following prehearing briefing, revocation proceedings were held July 28 and 29, 2014, and the matter is pending the ALJ's decision.

9. Following the denial of his certiorari petition in December of 2013, while I was representing in the Medical Board proceedings, Dr. Harkonen raised with me the subject of his mounting a collateral attack on his conviction based on the a claim of ineffective assistance of counsel ["IAC."].) Dr. Harkonen was not immediately in a financial position to retain counsel to

pursue such an action. Although the cost of mounting Dr. Harkonen's defense at trial and on appeal was almost entirely covered by a corporate indemnification policy, in the wake of the denial of petitioner's certiorari petition, InterMune took the position that coverage would not be extended to a collateral attack or further administrative proceedings. Furthermore, Intermune's insurance company has instituted an arbitration action against Dr. Harkonen and InterMune aimed at "clawing back" the monies expended on Dr. Harkonen's defense. I told Dr. Harkonen that I would investigate the feasibility of such an action while he obtained the funds to retain counsel for his representation.

10. In early February of 2014, I contacted Mark Haddad of the Sidley firm to see whether they intended to represent Dr. Harkonen is such an action. In a series of discussions over the following weeks, attorney Haddad informed me that there were institutional reasons that Sidley would be unable to represent Dr. Harkonen on a claim of ineffective assistance of counsel. Furthermore, attorney Haddad and his colleagues might well have to serve as fact witnesses in such an action, particularly on the issues that could arise concerning videotapes of the ERS and CHEST conferences. Haddad informed me that subsequent to his replacing Mark Topel as chief counsel for Dr. Harkonen in August of 2010, he requested all materials concerning the CHEST and Stockholm conferences that were in Topel's possession. At Doctor Harkonen's urging, on January 4th, 2011 Haddad renewed that request, specifically requesting the videotapes of the conferences that might have been provided to the Topel team by the government in discovery. Mr. Topel replied that he did not believe that his firm was or had been in possession of those tapes. On January 5 of 2011, Mr. Topel acknowledged that the CHEST and ERS videotapes had been produced in discovery in September of 2008 and arranged to have them delivered to the Sidley team.

11. On March 13, 2014, Don Horgan and Gary Dubcoff of my office, as well as myself, met with Dr. Harkonen for a lengthy discussion concerning our being retained to bring the collateral attack based on ineffective assistance of counsel. At that time, Doctor Harkonen

informed us that he would be able to retain counsel, and on April 1, 2014, I agreed to prepare the IAC claim. Dr. Harkonen forwarded me the necessary retainer fee on April 16, 2014.

12. I could not properly and competently prepare a collateral attack, or make a final decision as to its merits, without reviewing the files of, and discussing the relevant issues with, both attorney Topel and attorney Haddad. On April 9, 2014, I mailed Mr. Topel a letter requesting all files related to the Harkonen prosecution, which Mr. Topel agreed to provide.

13. On May 15, 2014, I interviewed Mark Haddad at the offices of Sidley, Austin in Los Angeles. Attorney Haddad agreed to provide me with materials in Sidley's files that might relate to the IAC issues that I was investigating.

14. On the following day, I interviewed Dr. Joseph Zibrak, who was in Los Angeles attending a medical conference, concerning his preparation to testify in 2009 at the trial of Dr. Harkonen. Doctor Zibrak informed me that he had been interviewed on more than one occasion in Boston by Lynn Agre, an attorney member of the Topel team; that he had had a substantive conversation concerning his testimony with Mark Topel but had not met with him face to face; and that he had flown to San Francisco during the trial expecting to testify. On the first day that he expected to be called, he was told that he might be called the following day. On the second day that he was available, he was told that he would not be needed as a witness, but was not given a reason for that decision.

15. On May 27, 2014, Mr. Topel's firm made available for pickup 250 boxes of files related to Dr. Harkonen's prosecution. On June 27th, the firm made available another 30 boxes of files and a electronic file containing 78,000 pages of email correspondence.

16. On Monday, July 14th, after reviewing a substantial portion of that material, I interviewed Mark Topel, Lynn Agre, and attorney William Goodman, all of who had been members of Doctor Harkonen's trial team, at their law office in San Francisco. My principal questions focused on their decision not to proffer expert evidence.

17. Attorney Topel stated that Dr. Lawrence Mayer was not called to testify as an expert

on biostatistics because, on the eve of his testimony, he retracted a key statement attributed to him in the defense's notice of experts filed on July 10, 2009. Mr. Topel had intended to call Mayer on the morning of Friday, September 18, 2009, the last day of testimony, when the cross-examination of defense witness Rosenfield was completed. But when Mr. Topel took Dr. Mayer through his proposed testimony after 4 p.m. on the afternoon of Thursday, September 17th, Mayer claimed to have rethought his position in a manner that weakened his testimony. For that reason, Mr. Topel decided not to call Dr. Mayer, who was paid a six figure fee for his services as an expert. The team also decided that they did not need to call Dr. Zibrak, who was readily available in San Francisco to testify on the 18th, or to seek a continuance to obtain the testimony of any of the other expert witnesses as to whom they had given notice to the court and government.

18. On June 16, 2014, the Food and Drug Administration issued a notice to Doctor Harkonen stating that, based on his federal fraud conviction, it intends to permanently ban him from participating in any matter pending before the agency. Dr. Harkonen has notified the FDA that he intends to contest the ban and has requested a hearing in order to do so.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, belief, and ability.

Executed this 30th day of July, 2014, in San Francisco, California.

Dennis P. Riordan